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Tuesday
July 9, 1996

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

WHO: Sponsored by the Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:
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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: July 23, 1996 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

Contents

Federal Register

Vol. 61, No. 132

Tuesday, July 9, 1996

Separate Parts In This Issue

Reader Aids
Additional information, including a list of public laws, telephone numbers, reminders, and finding aids, appears in the Reader Aids section at the end of this issue.

Electronic Bulletin Board
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.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

Rules and Regulations

Federal Register
Vol. 61, No. 132
Tuesday, July 9, 1996

FEDERAL DEPOSIT INSURANCE CORPORATION

5 CFR Part 3201

RIN 3064–AA08, 3209–AA15

Supplemental Standards of Ethical Conduct for Employees of the Federal Deposit Insurance Corporation

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Final rule.

SUMMARY: The Federal Deposit Insurance Corporation, with the concurrence of the Office of Government Ethics (OGE), is amending the Supplemental Standards of Ethical Conduct for Employees of the Federal Deposit Insurance Corporation in order to allow employees' spouses and minor children to acquire otherwise prohibited securities when they are acquired as part of compensation packages in connection with their employment. The amendment is being made retroactively effective as of the effective date of the FDIC's supplemental standards.

EFFECTIVE DATE: May 25, 1995.

FOR FURTHER INFORMATION CONTACT: Richard M. Handy, Assistant Executive Secretary (Ethics), (202) 898–7271, in the Office of the Executive Secretary of the FDIC.

SUPPLEMENTARY INFORMATION:

I. Background

On April 25, 1995, with the concurrence of OGE, the FDIC published as a final rule the Supplemental Standards of Ethical Conduct for Employees of the Federal Deposit Insurance Corporation which were effective May 25, 1995 (codified at 5 CFR part 3201). The final rule was issued to supplement OGE's Standards of Ethical Conduct for Employees of the Executive Branch that established uniform standards of ethical conduct for executive branch employees (effective February 3, 1993, and codified at 5 CFR part 2635).

Upon the determination of the Board of Directors and with the concurrence of OGE, part 3201 is being amended to provide an additional exception to the prohibitions on the ownership of securities of FDIC-insured depository institutions. The amendment allows spouses and minor children of employees to acquire otherwise prohibited securities when they are acquired as part of compensation packages in connection with their employment. The Board of Directors determined that the provision, without the revised language, was unnecessarily restrictive.

This rule is being issued as a final rule since it reduces the restrictions placed on employees and their families by the existing rule. Further, the amended rule will be made retroactively effective to May 25, 1995.

II. Matters of Regulatory Procedure

Administrative Procedure Act

Pursuant to 5 U.S.C. 553 (a)(2), (b) and (d), the Board of Directors has found that good cause exists for waiving the regular notice of proposed rulemaking and 30-day delayed effective date as to this final rule amendment, and further making it retroactively effective to May 25, 1995, the effective date of the overall part 3201. This action is being taken because it is in the public interest that this rule, which concerns matters of agency organization, practice and procedure and which relieves certain restrictions placed on FDIC employees and their families, become effective retroactively on the effective date of the original final rule.

Regulatory Flexibility Act

The Board of Directors has concluded that the amendment to the rule will not impose a significant economic hardship on small institutions. Therefore, the Board of Directors hereby certifies pursuant to section 605 of the Regulatory Flexibility Act (5 U.S.C. 605) that the amended regulation will not have a significant economic impact on a substantial number of small business entities within the meaning of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Paperwork Reduction Act

The Board of Directors has determined that the amended regulation does not contain any information collection requirements that require the approval of the Office of Management and Budget pursuant to the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

List of Subjects in 5 CFR Part 3201

Administrative practice and procedure, Conflict of interests, Government employees, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Federal Deposit Insurance Corporation, with the concurrence of the Office of Government Ethics, is amending 5 CFR part 3201 as follows:

PART 3201—SUPPLEMENTAL STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE FEDERAL DEPOSIT INSURANCE CORPORATION

1. The authority citation for part 3201 continues to read as follows:

Authority: 5 U.S.C. 7301; 5 U.S.C. App. (Ethics in Government Act of 1978); 12 U.S.C. 1819(a), 1822; 26 U.S.C. 1043; E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306; 5 CFR 2635.105, 2635.403, 2635.502, and 2635.803.

2. In § 3201.103, paragraph (b)(4) is amended by revising the first sentence to read as follows:

§ 3201.103 Prohibitions on ownership of securities of FDIC-insured depository institutions.

* * * * *

(b) * * *

(4) Acquiring, owning, or controlling a security of an FDIC-insured depository institution or the affiliate of an FDIC-insured depository institution where the security was acquired by inheritance, gift, stock split, involuntary stock dividend, merger, acquisition, or other change in corporate ownership, exercise of preemptive right, or otherwise without specific intent to acquire the security, or, by an employee's spouse or minor child as part of a compensation package in connection with his or her employment. * * *

* * * * *

Dated at Washington, D.C. this 17th day of June 1996.

By Order of the Board of Directors.

Federal Deposit Insurance Corporation.
Robert E. Feldman,
Deputy Executive Secretary.

Concurred in this 1st day of July 1996.
Stephen D. Potts,
Director, Office of Government Ethics.
[FR Doc. 96–17304 Filed 7–8–96; 8:45 am]
BILLING CODE 6714–01–P

DEPARTMENT OF AGRICULTURE

Rural Housing Service

Rural Business-Cooperative Service

Rural Utilities Service

Farm Service Agency

7 CFR Parts 1910, 1924, 1941, 1943, 1945, 1951, 1955, 1962, 1965, and 1980

RIN 0575–AB45

Loan Assessment, Market Placement, and Graduation of Direct Loan Borrowers

AGENCIES: Rural Housing Service, Rural Business-Cooperative Service, Rural Utilities Service, and Farm Service Agency, USDA.

ACTION: Interim rule with request for comments.

SUMMARY: The issuing USDA agencies are amending the direct and guaranteed farm loan regulations to implement changes to the Consolidated Farm and Rural Development Act (CONACT) as a result of the Food, Agriculture, Conservation, and Trade Act of 1990 (1990 Act) and the Agricultural Credit Improvement Act of 1992 (1992 Act). These amendments implement and coordinate ''loan assessment,'' ''market placement,'' and the ''graduation of seasoned direct loan borrowers to the loan guarantee program.'' The intended outcome is to improve the success rate of borrowers receiving Farm Service Agency (FSA) assistance and to facilitate their transitions to commercial credit.

DATES: Effective July 9, 1996. Comments must be submitted by October 7, 1996.

ADDRESSES: Submit written comments to Steven R. Bazzell, Senior Loan Officer, Farm Credit Programs Loan Making Division, Farm Service Agency (FSA) United States Department of Agriculture (USDA), Ag Box Code 0522, Room 5438 South Building, 14th Street and Independence Avenue, SW., Washington, DC. 20250–0522. Written comments made pursuant to this rule will be available for public inspection at the above address between 8:15 am and 4:45 pm, Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Bazzell of the Farm Credit Programs Loan Making Division at telephone (202) 720–3889, fax (202) 690–1117, or e-mail sbazzell@wdc.fsa.usda.gov.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This rule has been determined ''not significant'' for the purpose of complying with Executive Order 12866, and therefore, it has not been reviewed by the Office of Management and Budget (OMB).

Executive Order 12372

1. For the reasons set forth in the Notice related to 7 CFR part 3015, subpart V (48 FR 29115, June 24, 1983), Farm Ownership Loans, Farm Operating Loans, and Emergency Loans are excluded from the scope of Executive Order 12372, which requires intergovernmental consultation with State and local officials.

2. The Soil and Water Loan Program is subject to and has complied with the provisions of Executive Order 12372 and FmHA Instruction 1940–J.

Federal Assistance Programs

These changes affect the following FSA Farm Credit programs as listed in the Catalog of Federal Domestic Assistance:

10.404—Emergency Loans
10.406—Farm Operating Loans
10.407—Farm Ownership Loans
10.416—Soil and Water Loans

Environmental Impact Statement

This document has been reviewed in accordance with 7 CFR part 1940, subpart G, ''Environmental Program.'' The issuing agencies have determined that this action does not significantly affect the quality of the human environment, and in accordance with the National Environmental Policy Act of 1969, Public Law 91–190, an Environmental Impact Statement is not required.

Executive Order 12778

This interim rule has been reviewed under Executive Order 12778, Civil Justice Reform. In accordance with this rule: (1) All State and local laws and regulations that are in conflict with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings in accordance with the National Appeals Division appeal regulations at 7 CFR part 11 must be exhausted before bringing suit in court challenging action taken under this rule unless those regulations specifically allow bringing suit at an earlier time.

Paperwork Reduction Act

The information collection or recordkeeping requirements contained in these regulations have been approved by the Office of Management and Budget (OMB) under the provisions of 44 U.S.C. Chapter 35 and have been assigned OMB control numbers 0575–0134, 0575–0061, 0575–0141, 0575–0085, 0575–0083, 0575–0090, 0575–0093, 0575–0079 and 0575–0111 in accordance with the Paperwork Reduction Act of 1995. This interim rule does not revise or impose any new information collection or recordkeeping requirement from those approved by OMB.

This regulatory action is being taken as part of the National Performance Review program to eliminate unnecessary regulations and improve those that remain in force.

Discussion of the Interim Rule

On December 30, 1993, the Farmers Home Administration (FmHA) published a proposed rule in the Federal Register (58 FR 69274–69298) with a comment period that ended February 28, 1994. The purpose of this interim rule is to implement statutory provisions on loan assessment, market placement, and graduation of seasoned direct loan borrowers to the guaranteed loan program. These provisions were contained in the 1990 Act and the 1992 Act and affect former FmHA Farmer Programs. Due to the reorganization of USDA, responsibility for administering FmHA Farmer Programs has been transferred to FSA. Other loan programs formerly administered by FmHA will only be affected by general, conforming administrative revisions made to the regulations on receiving and processing applications and analyzing credit needs and graduation of borrowers. These programs include: Rural Housing loans now administered by the Rural Housing Service (RHS), Water and Waste Facility loans now administered by the Rural Utilities Service (RUS), and Business and Industrial loans and Intermediary Relending Program loans now administered by the Rural Business-Cooperative Service (RBS). FSA, RHS, RUS, and RBS are jointly issuing this interim rule since substantial administrative revisions have been made to regulations affecting their programs in an effort to reduce Agency regulations.

The issuing agencies are publishing these regulations as an interim rule and providing a 90-day comment period. The comment period will provide the public, including Agency field staff, the opportunity to use and evaluate the new

processes from a practical standpoint. We expect this will provide the Agency with many more valuable suggestions to consider prior to issuance of the final rule.

Discussion of Comments

In response to the proposed rule, 14 respondents provided 25 specific comments. Since few of the comments addressed the same issue, they have been grouped by the general regulatory areas to which they pertain, as follows: Borrower supervision and planning, chattel loan security, graduation to commercial credit, and guaranteed loans.

Borrower Supervision and Planning

One respondent stated that each borrower should submit the year's actual production and financial information, in addition to the projected budget, when the projected budget is being submitted for review and reclassification purposes only. The Agency has revised the regulations to require that actual production and financial performance information be submitted along with the borrower's projections. FSA agrees with the rationale that actual performance should be obtained whenever financial information is obtained from borrowers in order to monitor their financial progress. This is in line with the practices of commercial lenders and the goals of FSA's borrower training.

One respondent stated that the year-end analysis should ideally be done prior to the beginning of the next production cycle, but not later than 60 days after the end of the previous production cycle. FSA has revised the regulations to state that, whenever possible, the year-end analysis should be scheduled and completed not later than 60 days after the end of the borrower's business year or farm budget planning period. This change was made in recognition of the uncertainties of Agency staffing and the fluctuating nature of the demand for FSA Farm Credit assistance. It is impracticable to mandate that the year-end analysis be completed within the 60-day timeframe, without exception.

One respondent stated that a year-end analysis should be required on all recently serviced loans under subpart S of part 1951. The proposed regulations require that a year-end analysis be completed for all first-time, annual operating, delinquent, and limited resource interest rate borrowers. All other FSA Farm Credit borrowers were to receive a year-end analysis at the discretion of the Agency based upon the ''assessment'' of the needs and risks associated with each individual farming operation. In response to this comment, the Agency has revised the regulation to broaden coverage to require a year-end analysis the first year after the borrower: (1) Receives a new loan, chattel subordination or restructuring; (2) is determined delinquent or financially distressed; (3) has a loan deferred; or (4) receives limited resources interest rates. This change expands year-end analysis coverage to chattel subordinations and restructurings while mandating that it be performed only the first year when most problems arise. Chattel subordinations and restructurings will trigger a year-end analysis in the first year because of the increased risk to the Government. Thereafter, the Agency has the flexibility to perform the year-end analysis on a case-by-case basis based on the individual needs of each borrower.

One respondent stated that Exhibit A, Attachment 1, of subpart B of part 1924 of this chapter should be modified to inform the farm borrower that budget plans other than the Form FmHA 432–1, ''Farm and Home Plan,'' may be used. This Exhibit A letter is, however, used exclusively to inform borrowers of their rights and responsibilities in regard to the disposition of security. Since Exhibit A does not pertain to farm budgeting, no changes will be made in response to this comment. The Agency plans to remove this exhibit from the regulations in the final rule.

Three respondents made a general statement that there are inadequate staff resources at the county office level to carry out the provisions of these regulations in a timely manner. The Agency has eliminated several regulatory requirements to provide expanded discretion to county office personnel, such as the elimination of mandatory accounting updates and field visits. Such administrative procedures have been removed from the regulations, but will be addressed in internal agency instructions. Additional administrative reductions may be considered for future regulatory revisions, after the Agency has empirical evidence to determine the effectiveness of the current regulatory changes. Therefore, no changes will be made by the Agency at this time.

One respondent stated that FSA should accept an applicant's self-certification with regard to environmental compliance. Currently, Agency personnel, or lenders in the case of guaranteed loans, are required to make a visual inspection of the farming operation as part of the environmental compliance process. Generally, environmental statutes place the burden on the Federal Government for compliance. This responsibility cannot be delegated to individual applicants without statutory authority. No change will be made.

One respondent stated that ''production cycle,'' as the term is used in conducting the year-end analysis under § 1924.55(d)(1) should be defined as the completion of the farm budget planning period. The Agency agrees that this could be potentially confusing and has revised § 1924.55(d)(1) to clarify ''production cycle'' to mean ''farm budget planning period.''

Chattel Loan Security

One respondent stated that § 1924.56(b)(5) should be clarified to state that during an appeal, FSA will release normal income security to allow the borrower to pay essential family living and farm operating expenses, except for the expenses which are the subject of the appeal. The Agency agrees that this could be misunderstood and has referenced this paragraph back to subpart A of part 1962.

Three respondents stated that the FSA regulations require that notices be filed (for lien perfection) under both the Uniform Commercial Code (UCC) and Central Filing System (CFS), where implemented, which in their opinion has no significant benefit. The respondents stated that filing under both systems should be used on a discretionary basis for problem accounts only. The most common practice among commercial lenders is to file notices under both the UCC and CFS. FSA will follow this same conventional practice, and no changes will be made in Agency procedure. Section 1962.5, describes which filing procedures for financing statements and other internal procedures for handling security instruments, has been removed but will be covered by internal Agency instructions.

One respondent stated that § 1924.57 should be revised to state that Agency personnel may provide credit counseling rather than will provide credit counseling. This suggestion is not being adopted in internal agency instructions since it is the Agency's responsibility to provide credit counseling as needed by individual farm borrowers. This administrative section has been removed from the regulations.

One respondent stated that the regulations should allow more Agency discretion on conducting field visits, year-end analyses, credit counseling, etc. The Agency has already eliminated required numbers of field visits, collateral inspections (when justified

and documented in the case file), accounting updates, etc., and has directed that these activities be derived directly from the farm assessment. No further changes in this regard will be made until empirical evidence can be examined by the Agency with regard to the effectiveness of the current revisions.

One respondent stated that borrowers who are not required to undergo a year-end analysis should only be required to submit an annual balance sheet and that it is unreasonable to require these borrowers to submit a projected cash flow for the upcoming year for borrower classification purposes. FSA is required by the 1992 Act to reclassify ''seasoned direct borrowers'' for the purpose of graduation, and the projected cash flow is needed to classify borrowers; therefore, FSA will make no changes with respect to the financial information needed. However, FSA has revised the regulations to require these ''classification only'' borrowers to submit their full set of financial statements only every 2 years. In intervening years when financial statements are not obtained, the Agency will make a desk review of the borrower's case file and determine whether graduation efforts should be pursued according to internal Agency instructions. Full financial information will be required automatically only every 2 years because based on past experience a borrower's ability to graduate generally does not change significantly from 1 year to the next. This will meet the requirements of the statute, while reducing the burden on field staff resources and borrowers. The Agency expects this approach to actually enable the county offices to graduate more direct borrowers to commercial credit because there will be more time available to perform a more thorough graduation review and to more vigorously pursue graduation through Market Placement.

Two respondents commented that § 1924.56 needs clarification, especially with regard to the derivation and use of production yields. FSA agrees and has revised this regulation to clarify that 5 years of actual production history will be used as a guide when preparing and evaluating a farm business plan. This clarification has been made to stress that, while historical information is extremely useful, the analysis of an agricultural operation's production trends and current capabilities must be considered.

One respondent suggested that the existing Form FmHA 431–2, ''Farm and Home Plan,'' be revised to incorporate Form FmHA 1962–1, ''Agreement for Use of Proceeds/Release of Chattel Security.'' FSA will give this suggestion consideration for future improvements, but no changes will be made at this time. Form FmHA 1962–1 has been removed as an exhibit to part 1962, subpart A, but will be available in any Agency office.

Graduation to Commercial Credit

One respondent stated that only borrowers classified as commercial should be considered candidates for graduation to commercial credit. No change will be made since the Consolidated Farm and Rural Development Act section 333A(f) (7 U.S.C. 1983a(f)) specifies that both commercial and standard classified borrowers be considered for graduation.

One respondent stated that the proposed regulations require all commercial and standard classified borrowers to have an assessment completed or updated. The respondent recommended that an assessment not automatically be required. The respondent suggested that a current balance sheet, actual performance for the most recent year, and a projected farm budget should instead be used to determine graduation potential and for preparation of the prospectus to lenders. FSA agrees with the logic of this recommendation and has revised § 1951.262 and the definition of ''prospectus.'' Many graduation candidates will not need a complete or updated assessment, as described under subpart B of part 1924, when the sole purpose is pursuing graduation to commercial credit.

One respondent stated that the language ''reasonable rates and terms'' should not be changed to ''prevailing rates and terms'' in subpart F of part 1951 because the former language is defined by regulation and it is contained in various loan documents, particularly in the Community and Business Programs. FSA agrees and will not delete ''reasonable rates and terms'' from this regulation.

One respondent stated that farm borrowers should be charged commercial interest rates when it appears that they are able to graduate to commercial credit. Otherwise, the respondent stated, there is no incentive for borrowers to graduate. Subpart A of part 1951 presently requires that direct borrowers be charged FSA's ''regular'' interest rate when they attain a 10-percent repayment margin. This interest rate is comparable to commercial lending rates, therefore, no change will be made.

Guaranteed Loans

The last respondent stated that under § 1980.113, the term ''current balance sheet'' should be defined as one that is less than 90 days old on the date the Agency receives a complete application. FSA agrees that this should be clarified and has revised the regulation accordingly.

Miscellaneous Changes

In addition to the changes made as a result of public comments, FSA has made several changes to further streamline or, in some cases, clarify the intent of the regulations as discussed below.

The 5-year budget project projection also is being eliminated as a general requirement for all FCP borrowers and applicants. The 5-year budget will instead be used as a counseling tool by the Agency, as appropriate, under internal Agency instructions. This change is in keeping with the Agency's movement toward fewer regulatory requirements and more discretion for Agency personnel.

Section 1924.55 is being clarified to state that many components of the assessment will be inapplicable to the Youth Loan program since these applicants and borrowers are not conducting farming or ranching operations. Year-end analyses for Youth loans are also being made a discretionary activity for Agency personnel since these loans are used to make small purchases for mainly educational purposes, e.g., raising and selling one pig or cow for a 4–H project.

''Flagged Accounts'' are being eliminated as needing mandatory year-end analyses under § 1924.55. Flagged accounts include such accounts as bankruptcies and foreclosure actions pending. In such cases, contact with the borrower may be constrained by a court, or the farming operation may be in some stage of liquidation and, therefore, no longer an ongoing business concern. Therefore, flagged accounts will have a year-end analysis performed only at the discretion of the Agency.

Section 1924.55 also has been revised to state that in the case of existing borrowers, an assessment should be made at the time of the year-end analyses if no assessment has yet been done. An earlier assessment would have been done if the borrower had been found eligible for another loan, for example. The mandatory assessment provision was removed for existing borrowers in order to permit an administrative phase-in of the assessment process over a three year period for most existing borrowers.

Borrowers with flagged accounts would receive assessments only when and if year-end analyses were performed in accordance with this revised section. (The reason for the flagged account exception is discussed above.) This policy is permissible under CONACT section 360 which only requires initial assessments of eligible applicants and follow-up reviews of the new borrowers. The phase-in will promote high quality assessments by field offices and allow them to focus on new borrowers. The Agency is unable because of fiscal constraints to take advantage of its statutory authority to contract out loan assessments.

A minor revision was made with regard to the market placement regulations in the guaranteed loan program. The requirement for the submission of the applicant's or borrower's assessment to the lender was deleted since the Agency will prepare the guaranteed application on the lender's behalf. The Market Placement Application described under § 1980.113 also was revised to make it more concise. Upon further Agency review, it was determined that the individual line items describing the application were unnecessary. This now states Form FmHA 1980–25, which is the guaranteed loan application, along with all other items listed in this section with the exception of the loan or line of credit agreement, are required. The loan assessment is prepared by the Agency as part of the items required in the narrative summary under § 1980.113(a)(12).

Section 1910.4 has been revised to implement a requirement of the Federal Debt Collection Act of 1990. Under this statute, an applicant is ineligible for a loan if the applicant has an outstanding recorded judgment against them by the United States in a Federal Court other than the United States Tax Court.

Section 1910.5 has been revised to clarify how bankruptcy is used in determining the acceptability of an applicant's credit history. The key is not the bankruptcy itself, but rather the circumstances behind it. If they were beyond the borrower's control, then they are not considered an indication of unacceptable credit history.

References to the FmHA County Committee and its certification of a borrower or applicant's farm loan eligibility for five years have been removed. FmHA County Committees and the mandate to make 5 year certifications of eligibility were abolished by section 227(b) of the Department of Agriculture Reorganization Act of 1994. The functions performed by the FmHA County Committee in relation to Farmer Programs loans now will be performed by the Agency. ''Agency'' has been defined in the regulations to include FSA county or area committees established in accordance with section 8(b) of the Soil Conservation and Domestic Allotment Act (16 U.S.C. 590h(b)). Loan eligibility will be determined for each loan application.

Regulations being changed to implement loan assessment, market placement, and graduation policies also were substantially revised to remove administrative procedures. These procedures instead will be covered solely by the Agency's internal instructions.

The Agency intends to remove exhibits being revised by this interim rule in the final rule. Any substantive policy will be covered in the regulation text. Forms will remain available in any Agency office.

List of Subjects

7 CFR Part 1910

Agriculture, Applications, Credit, Loan programs—Housing and community development, Low and moderate income housing, Marital status discrimination, Sex discrimination.

7 CFR Part 1924

Agriculture, Construction management, Construction and repair, Energy conservation, Housing, Housing and community development, Loan programs—Low and moderate income housing.

7 CFR Part 1941

Agriculture, Crops, Livestock, Loan programs—Rural areas, Youth.

7 CFR Part 1943

Agriculture, Credit Loan Programs—Recreation and recreation areas, Water resources.

7 CFR Part 1945

Agriculture, Disaster assistance, Loan programs.

7 CFR Part 1951

Account servicing, Agriculture, Credit, Debt restructuring, Loan programs—Housing and community development, Low and moderate income housing loans—Servicing.

7 CFR Part 1955

Government acquired property, Government property management.

7 CFR Part 1962

Agriculture, Crops, Government property, Livestock, Loan programs—Rural areas.

7 CFR Part 1965

Agriculture, Foreclosure, Loan programs—Rural areas.

7 CFR Part 1980

Agriculture, Loan programs.

Accordingly, Chapter XVIII, Title 7, Code of Federal Regulations is amended as follows:

PART 1910—GENERAL

1. The authority citation for part 1910 is revised to read as follows:

Authority: 5 U.S.C. 301; 7 U.S.C. 1989; and 42 U.S.C. 1480.

Subpart A—Receiving and Processing Applications

2. Section 1910.1 introductory paragraph is amended:

a. by removing the phrase ''Farmers Home Administration or its successor agency under Public Law 103–354 (FmHA or its successor agency under Public Law 103–354)'' and adding the words ''Farm Service Agency (FSA) and Rural Housing Service (RHS)'' in its place;

b. by removing the words ''Farmer Programs'' and adding the words ''Farm Credit Programs'' in its place;

c. by removing the phrase ''FmHA or its successor agency under Public Law 103–354'' in paragraph (a) and adding the words ''FSA and RHS'' in its place; and revising paragraph (c) and adding paragraph (e) to read as follows:

§ 1910.1 General.

* * * * *

(c) FmHA forms are available in any Rural Development (RD) or FSA office.

* * * * *

(e) As used in this subpart in relation to Farm Credit Programs loans, *Agency* means the Farm Service Agency, its county and State committees and their personnel, and any successor agency.

3. In § 1910.3:

a. the introductory text and paragraph (a), introductory text, are amended by removing the phrase ''FmHA or its successor agency under Public Law 103–354'' and adding the words ''FSA or RHS'' in their place;

b. all references to ''or its successor agency under Public Law 103–354'' in paragraphs (a)(1), (a)(2), and (a)(4)(i) are removed; and references to ''FmHA or its successor agency under Public Law 103–354'' are removed and ''RD'' is added in their place, the first time it

appears in paragraph (a)(4)(i) and in paragraph (a)(4)(ii).

4. Section 1910.4 is amended by:

a. removing paragraph (h);

b. redesignating paragraphs (c) through (g) as (d) through (h), respectively;

c. removing the words ''Farmer Programs'' in redesignated paragraphs (d), (k) introductory text and (k)(3) and adding the words ''Farm Credit Programs;'' in its place;

d. removing the words ''FmHA or its successor agency under Public Law in paragraph (k)(4) and adding the words ''the Agency'' in its place; and

e. removing the language appearing in the parentheticals in redesignated paragraphs (d)(3)(i), introductory text, (d)(3)(iii), introductory text, (d)(3)(v) and (k)(4).

5. Section 1910.4 paragraphs (k)(1), (k)(4) and redesignated (d)(1), (d)(3)(i), (d)(3)(iii), introductory text, and (d)(3)(v) are amended by removing the phrase ''or its successor agency under Public Law 103–354.''

6. In § 1910.4 paragraph (k)(3) the reference ''paragraph (c)'' is removed and the reference ''paragraph (d)'' is added in its place; removing and reserving paragraph (j); revising redesignated paragraphs (e), (f), (g), and (h), and paragraphs (b), (i)(1), (i)(1)(i), (i)(1)(ii)(B), (i)(5) and adding new paragraph (c) to read as follows:

§ 1910.4 Processing applications.

* * * * *

(b) *Completed Farm Credit Programs applications and additional FSA responsibilities.* All persons requesting an application will be provided Exhibit A (available in any office). The County Supervisor will provide assistance as necessary to help applicants complete their applications. Complete applications will be processed in the order of date received, except as outlined in Section 1910.10 of this subpart. If the application is complete when it is first received, a County Office official will stamp the filing date on the front of Form FmHA 410–1 and enter the date in the ''Application Received'' and ''Application Completed'' fields in the Application Processing Module of the Management Records Systems (MRS.) On the date all information necessary to process an application is received, a County Office official will send the applicant FmHA Guide Letter 1910–A–3 (available in any office) notifying the applicant that the application is considered complete. The date entered in the ''Application Completed'' field in the Application Processing Module of MRS will establish the 30-day and 60-day timeframes for determining eligibility and loan approval/disapproval, respectively. The County Supervisor will verify the information furnished by the applicant, and record and assemble additional information needed to properly evaluate the applicant's qualifications and credit needs. Additional information may be obtained and verified by County Office records, personal contacts, and visits to the applicant's operation. A complete Farm Credit Programs application requires fulfillment of both the applicant and FSA responsibilities. Once this information is received and the application is considered complete, FSA has additional responsibilities before loan approval is determined. The various responsibilities are as follows:

Applicant's Responsibilities for a Complete Application

(1) Completed Form FmHA 410–1, ''Application for FmHA Services,'' including a signed Form FmHA 410–9, ''Statement Required by the Privacy Act.''

(2) If the applicant is a cooperative, corporation, partnership, or joint operation:

(i) A complete list of members, stockholders, partners or joint operators showing the address, citizenship, principal occupation, and the number of shares and percentage of ownership or of stock held in the cooperative or corporation, by each, or the percentage of interest held in the partnership or joint operation, by each.

(ii) A current personal financial statement from each of the members of a cooperative, stockholders of a corporation, partners of a partnership, or joint operators of a joint operation.

(iii) A current financial statement from the cooperative, corporation, partnership, or joint operation itself.

(iv) A copy of the cooperative's or corporation's charter, or any partnership or joint operation agreement, any articles of incorporation and bylaws, any certificate or evidence of current registration (good standing), and a resolution(s) adopted by the Board of Directors or members or stockholders authorizing specified officers of the cooperative, corporation, partnership, or joint operation to apply for and obtain the desired loan and execute required debt, security, and other instruments and agreements.

(3) A brief written description as to the farm training and/or experience of the applicant and the individual members of an entity applicant (new applicants only). If a waiver from the training required in Section 1924.74 of subpart B of part 1924 of this chapter is requested, provide verification of any courses taken which covered production and/or financial management concepts, and/or a statement explaining how the applicant's proven performance based on 5-year production records demonstrates production ability.

(4) Supporting and documented verification that the applicant (and all members of an entity applicant) cannot obtain credit elsewhere, including a guaranteed loan.

(5) Financial records for the past five years. Income tax records may be provided by the applicant when other financial records are not available.

(6) Five years of production history immediately preceding the year of application, unless the applicant has been farming less than 5 years.

(7) A brief written description of the proposed operation and the proposed size of the operation (required for new applicants and existing borrowers with significant changes in their operations).

(8) Verification of off-farm employment, if any. This will be used only when the applicant is relying on off-farm income to pay part of the applicant's expenses.

(9) Projected production, income and expenses, and loan repayment plan, which may be submitted on Form FmHA 431–2, ''Farm and Home Plan,'' or other similar plans of operation acceptable to FSA.

(10) Applicable items required in Exhibit M of subpart G of part 1940 of this chapter including SCS Form CPA–026, ''Highly Erodible Land and Wetland Conservation Determination,'' Form AD–1026, ''Highly Erodible Land Conservation (HELC) and Wetland Conservation (WC) Certification,'' and Form FmHA 1940–20, as required by subpart G of part 1940 of this chapter.

(11) A legal description of farm, real estate property and/or (if applicable) a copy of any lease, contract, option or agreement entered into by the applicant which may be pertinent to consideration of the application, or when a written lease is not obtainable, a statement setting forth the terms and conditions of the agreement.

(12) Form FmHA 440–32, ''Request for Statement of Debts and Collateral,'' when applicable.

(13) Forms FmHA 1945–22, ''Certification of Disaster Losses,'' and FmHA 1940–38, ''Request for Lender's Verification of Loan Application,'' (EM loans only).

FSA's Responsibilities for a Complete Application

(14) Send Form FmHA 410–7, ''Notification to Applicant on Use of Financial Information from Financial

Institution,'' to the applicant when applicable.

(15) Form FmHA 1945–26, ''Calculation of Actual Losses'' (EM loans only).

(16) Credit reports as provided in subparts B and C of this part.

(17) Form FmHA 1945–29, ''ASCS Verification of Farm Acreages, Production and Benefits,'' (EM loans only).

(18) The Current/Past Debt Inquiry and Borrower Cross-Reference Systems. The Current/Past Debt Inquiry System must be reviewed for each application and copies of the screens must be attached to the applicant's file.

(19) For special beginning farmer or rancher operating (OL) loan assistance, a plan of operation will be developed for each of the first 5 years for which such assistance is requested. A projection of the financial status of the operation showing financial viability within the commitment period will also be developed. The 5-year plan and projection will be developed as described in § 1941.15. This information will be presented on reports generated on the automated Farm and Home Plan system, or in other plans or documents consistent and acceptable to the Agency.

Additional FSA Farm Credit Responsibilities

(20) Form FmHA 1924–1, ''Development Plan,'' if necessary.

(21) Form FmHA 1940–22, ''Environmental Checklist for Categorical Exclusions,'' or Class I and Class II assessment, whichever is applicable.

(22) Real estate and chattel appraisal, when applicable.

(23) Completion of the assessment in accordance with § 1924.55.

(c) *Notifying applicants that direct loan eligibility is subject to the unavailability of guaranteed financing.* If the assessment, completed in accordance with § 1924.55 concludes that guaranteed assistance may be available, with or without interest assistance, a prospectus will be sent to area lenders in accordance with § 1951.262 (f) as appropriate. If a lender indicates interest in providing financing with a Farm Credit Programs loan guarantee, refer to § 1980.113 (c) for handling as a market placement application. No direct loan to a current borrower will be approved until the process outlined in this paragraph has been concluded.

* * * * *

(e) *Notifying applicants (including presently indebted borrowers) about Limited Resource loans.* Immediately after an application for OL, FO, SW, or EM assistance is received, the County Supervisor will send a letter similar to Guide Letter 1924–B–1 to the applicant telling the applicant about Limited Resource loans.

(f) *Notifying socially disadvantaged applicants regarding the availability of Direct Farm Ownership (FO) loans and the acquisition/leasing of Agency acquired farmland.* Immediately after an application for FO assistance is received, the County Supervisor will send Exhibit B of this subpart, ''Letter to Notify Socially Disadvantaged Applicants/Borrowers Regarding the Availability of Acquired Farmland,'' to the applicants. Exhibit B will also be presented to all socially disadvantaged individuals at the time they make their initial contact regarding Agency credit services. Socially disadvantaged applicants are defined in Section 1943.4 of subpart A of part 1943 of this chapter.

(g) *Notifying Borrowers about Farm Credit Programs (FCP) Borrower Responsibilities.* When an application for OL, FO, SW or EM assistance is approved, the County Supervisor will provide to the borrower Exhibit C of this subpart, ''Letter to Notify Applicant(s)/Borrower(s) of Their Responsibilities in Connection with FmHA Farmer Programs Loans.''

(h) *Determining eligibility.* The Agency will determine eligibility of all Farm Credit Programs applicants including those who are already indebted for a Farm Credit Programs loan. The Farm Credit Programs application does not need to be complete before it is reviewed; however, all information relative to the eligibility decision must be received. The Rural Housing Service will determine eligibility for all RH loan applicants.

(1) The Agency will certify whether or not the applicant meets the eligibility requirements and whether or not the applicant is a beginning farmer or rancher, as defined in the applicable Farm Credit Programs loan making regulation. An eligible Operating Loan (OL) or Farm Ownership (FO) Loan applicant, who is considered a beginning farmer or rancher, will have access to targeted funds. An eligible FO applicant requesting to purchase suitable farmland, who is considered a beginning farmer or rancher, will be given priority in accordance with § 1955.107 (f). In addition, it is the responsibility of the Agency to determine whether or not the FO applicant is an operator of not larger than a family size farm, as of the time immediately after the contract of sale or lease is entered into, even though the applicant is not in need of Agency credit assistance on eligible rates and terms to purchase suitable farmland. The loan approval official will determine the applicant's projected repayment ability, the adequacy of collateral equity to secure the requested loan, and the feasibility of the proposed operation.

(2) An outstanding judgment obtained by the United States in a Federal Court (other than the United States Tax Court), which has been recorded, shall cause the applicant to be ineligible for any loan or grant until the judgment is paid in full or otherwise satisfied. Agency loan or grant funds may not be used to satisfy the judgment.

(i) * * *

(1) *Farm Credit Programs (FCP) applications.* Each application must be approved or disapproved and the applicant notified in writing of the action taken, not later than 60 days after receipt of a complete application. The District Director will monitor the processing of all applications to ensure that each is processed in a timely manner and receives a final disposition (i.e., approval, rejection, or withdrawal) within the timeframes outlined in this section.

(i) Receipt by the applicant of a signed copy of Form FmHA 1940–1, ''Request for Obligation of Funds,'' will be considered written notice of loan approval.

(ii) * * *

(A) * * *

(B) Every week the District Director will generate a report, using the FOCUS Ad-Hoc Reporting System, based on the weekly upload of information from each county office MRS data base. The District Director will note each complete application pending more than 45 calendar days, and immediately take steps to ensure that final disposition on the application is taken no later than 60 calendar days after receipt of the complete application.

* * * * *

(5) *Adverse decisions.* If an applicant is given an adverse decision, the applicant will be given appeal rights as provided in Subpart B of Part 1900 or 7 CFR part 780, as appropriate. The letter will contain the ECOA statement set forth in Section 1910.6(b)(1) of this subpart.

* * * * *

7. Section 1910.5 is amended:

a. by removing the phrase ''FmHA or its successor agency under Public Law 103–354'' in paragraph (c)(1) and adding the word ''Agency,'' in its place;

b. removing the word ''bankruptcy'' in paragraph (c)(4) introductory text, and

c. revising paragraph (c)(5) to read as follows:

§ 1910.5 Evaluating applications.

* * * * *

(c) * * *

(5) Non-payment of a debt due to circumstances beyond the applicant's or borrower's control. However, non-payment of a debt due to circumstances within an applicant's or borrower's control may be used as an indication of unacceptable credit history, in accordance with paragraph (c)(1) of this section. The mere fact that an applicant or borrower filed bankruptcy will not be used as an indication of unacceptable credit history. The circumstances causing the nonpayment of debt, i.e., whether nonpayment was beyond the applicant's or borrower's control, however, are proper considerations.

* * * * *

§§ 1910.6 through 1910.9 [Removed and Reserved]

8. In part 1910 §§ 1910.6 through 1910.9 are removed and reserved.

§ 1910.10 [Amended]

9. Section 1910.10(b) is amended by removing the words ''Farmer Program'' and adding the words ''Farm Credit Programs (FCP)'' in its place.

10. Section 1910.11 is revised to read as follows:

§ 1910.11 Special requirements.

(a) *Servicemen's Readjustment Act of 1944.* Section 512(a)(D) of the Servicemen's Readjustment Act of 1944, as amended, provides that an applicant for a direct housing loan from the Department of Veterans Affairs (VA) must be ''unable to obtain a loan for such purposes from the Secretary of Agriculture under the Consolidated Farm and Rural Development Act, as amended, or the Housing Act of 1949, as amended.'' Department of Veterans Affairs Loan Guaranty Officers may, therefore, require VA loan applicants to apply to the agency for loan assistance.

(b) *Veterans determined ineligible by the Agency.* If the veteran is unable to obtain a loan, the County Supervisor will, upon request, furnish the applicant with a rejection letter to be presented to the Loan Guaranty Officer. The Loan Guaranty Officer may consult with the County Supervisor regarding the investigation made by the Agency of the veteran's application and the specific reasons for rejection.

PART 1924—CONSTRUCTION AND REPAIR

11. The authority citation for part 1924 is revised to read as follows:

Authority: 5 U.S.C. 301; 7 U.S.C. 1989 and 42 U.S.C. 1480.

Subpart B—Management Advice to Individual Borrowers and Applicants

12. Section 1924.51 is revised and §§ 1924.54 and 55 are added to read as follows:

§ 1924.51 General.

This subpart contains policies for providing management advice to all Farm Credit Programs direct loan applicants and borrowers. Forms and Farm Assessment and Supervision Reference handbooks are available in any Agency county office.

§ 1924.54 Definitions.

As used in this subpart, the following definitions apply:

Agency. This term refers to the Farm Service Agency, its county and State committees and their personnel, and any successor agency.

Commercial classified. The Agency's highest quality Farm Credit programs accounts. The financial condition of the borrowers is strong enough to enable them to absorb the normal adversities of agricultural production and marketing. There is ample security for all loans, there is sufficient cash flow to meet the expenses of the agricultural enterprise and the financial needs of the family, and to service debts. The account is of such quality that commercial lenders would likely view the loans as a profitable investment.

Farm Assessment and Supervision Reference. This reference provides guidance to field staff on conducting assessments, year-end analyses, and general borrower supervision.

Farm business plan. The automated or manual Farm and Home Plan system which contains a projection that accurately reflects the borrower's plan of operation for the production or marketing cycle. The annual plan may cover a period of more or less than 12 months. A normal year's plan, as defined in this section, will be used when the annual plan does not reflect typical income, expenses, and debt payments. The Agency will accept farm business plans other than the Farm and Home Plan if they provide sufficient information to enable Agency officials to render a sound credit decision in accordance with Agency regulations.

Farm Credit Programs loan. Includes Farm Ownership (FO), Soil and Water (SW), Operating (OL), Emergency (EM), Economic Emergency (EE), Recreation (RL), Special Livestock (SL), Economic Opportunity (EO) and Softwood Timber (ST) loans. Also included are Rural Housing loans for farm service buildings (RHF), and Rural Housing (RH) loans where the borrower is also indebted for an Agency direct farm loan that is not a collection only or judgment account. Non-Program loans, which are defined in § 1951.451(a), are excluded.

Financially viable operation. A financially viable operation projects that it can generate sufficient income to meet annual operating expenses and debt payments as they become due, meet basic family living expenses to the extent they are not met by dependable non-farm income, provide for the replacement of capital items, and provide for long-term financial progress to enable the operator to obtain commercial credit.

Individual. The term ''individual'' is used throughout this subpart to refer to the person receiving Agency supervision and management advice. If an applicant or borrower applies as an individual applicant, the term ''individual'' means the operator. In the case of an eligible corporation, cooperative, partnership, or joint operation, the term ''individual'' means the entity members with the primary responsibility for making management decisions and carrying out the day-to-day physical tasks.

Normal year plan. A projected farm business plan most representative, or typical, of an operation's normal income, expenses (including family living expenses), and capital debt payments.

Prospectus. Consists of a transmittal letter similar to FmHA Guide Letter 1951–F–3 with a current balance sheet and projected year's budget attached. The applicant or borrower name and address need not be withheld from the lender. The prospectus is used to determine lender interest in financing or refinancing specific direct loan applicants and borrowers. The prospectus will provide information regarding the availability of Agency loan guarantee and interest assistance.

Standard classified. These loan accounts are fully acceptable by Agency standards. Loan risk and potential loan servicing costs are higher than would be acceptable to other lenders, but all loans are adequately secured. Repayment ability is adequate, and there is a high probability that all loans will be repaid as scheduled and in full.

§ 1924.55 Assessment of the agricultural operation.

Assessments will be completed for direct Farm Credit Programs loan applicants. An assessment is a comprehensive evaluation of the components of an operation, the identification and prioritization of training and supervisory needs, and the resulting plan of supervision to assist

the borrower in achieving financial viability. The assessment is the central foundation upon which to build strategies for planning, credit and management counseling, loan controls, analysis, borrower training, and all other needed supervision. An assessment will include thorough inspections of the operation and face-to-face meetings and discussions with all key individuals. At least semi-annual reviews of progress will be performed in accordance with paragraph (e) of this section.

(a) *Agency evaluation*. The Agency will assess each of the areas described in paragraph (b) of this section in close cooperation with the applicant or borrower. As part of that assessment, the Agency will determine whether the proposed budget is feasible on a direct or guaranteed loan basis, the type and nature of any material financial or production management weaknesses in the operation, and the specific strategy needed, including timeframes, to effect improvements and control risks. Material weaknesses are those that have a significant impact on the net income of the operation and need to be corrected to enable the borrower to progress financially and eventually graduate from FSA farm credit programs. Examples of material weaknesses include, but are not limited to: lack of a farm recordkeeping system, obsolete or inadequate facilities, and use of outdated production practices. In the case of Youth loans, it is recognized that most of the component areas will be ''Not Applicable'' since there is no full-scale farming operation to consider.

(b) *The assessment is an evaluation, conducted with an applicant or borrower, of the following components*:

(1) Type of operation.

(2) Goals.

(3) Real estate, including facilities.

(i) Location and size.

(ii) Proposed and existing improvements.

(iii) Presence of environmental hazards.

(iv) Conservation practices and measures.

(v) Adequacy and continued availability of real estate.

(vi) External factors, such as urban encroachment and zoning changes.

(4) Chattel property used in the operation.

(5) Farm business organization and key personnel.

(6) Historical financial data.

(7) Projected budget.

(8) Planned changes.

(9) Ability to obtain guaranteed credit.

(c) *Supervision and training.* Appropriate supervisory oversight and training recommendations will be developed based on the Agency's evaluation of the strengths and weaknesses of the operation in accordance with paragraphs (a) and (b) of this section and § 1924.59.

(d) *Performing the year-end analysis.* A year-end analysis is required for borrowers (except for Youth loans and loans flagged as having bankruptcy, foreclosure, or other action pending) the first year after an initial or subsequent loan, chattel subordination, or restructuring is received, borrowers who are financially distressed or delinquent, borrowers who have loans deferred, and borrowers who are receiving limited resource interest rates. All other borrowers (including flagged accounts) will receive a year-end analysis at the discretion and judgment of the Agency. However, at least every two years, the borrower will provide upon Agency request, a year-end balance sheet, actual financial performance, and a projected farm budget so that the borrower can be classified for graduation purposes in accordance with subpart F of part 1951. The year-end analysis should coincide with the borrower's farm budget planning period. The borrower will work with the Agency to:

(1) Complete the year-end analysis, whenever possible, within the 60-day period after completion of the borrower's business year or farm budget planning period.

(2) Complete and review the ''actual'' columns on the farm business plan and Form FmHA 1962–1, ''Agreement for the Use of Proceeds/Release of Chattel Security,'' if applicable.

(3) Develop a farm business plan for the next production cycle in accordance with § 1924.56.

(4) Reach agreement on key management issues. Any such agreements will be documented for the borrower case file and signed by the borrower.

(e) *For all borrowers, the assessment described under this section will be reviewed on at least a semi-annual basis to monitor progress.* The borrower will consult with the Agency official in person, or if that is not possible, by telephone, or in writing. A meeting must be scheduled as soon as practicable to determine corrective options if: the borrower is, or expects to be, delinquent; the borrower is experiencing difficulties; or other significant changes have occurred. The year-end analysis under this section may be treated as one of the required assessment reviews.

13. Sections 1924.56 through 1924.60 are revised to read as follows:

§ 1924.56 Farm business planning.

The automated Farm and Home Plan system is the primary tool used by the Agency to evaluate loan feasibility and prospects for achieving financial viability. Other manual or automated business planning systems may be used with the consent of the Agency.

(a) [Reserved].

(b) *Documentation and revision of plans.* Individuals must submit a farm business plan to the Agency, upon request, for loan approval and servicing purposes. An individual may request the assistance of the Agency official, as needed, in completing the plan. Farm business plans will be based only on accurate, verifiable information. If the Agency official and the individual cannot reach agreement, on the farm business plan, then the Agency will make loan approval and servicing determinations based on the Agency's separate, revised farm business plan. The individual will have the right to appeal any resulting adverse decision.

(1) Historical information will be used as a guide to evaluate the feasibility of projected farm business plans. Individuals must provide the Agency with their previous 5-year production history, if available. Positive and negative trends, mutually agreed upon changes and improvements, and current input prices, will be taken into consideration when arriving at reasonable projections.

(i) For individuals with less than a 5-year history, actual production records from an operation to be taken over by the individual will be considered, whenever available.

(ii) In the absence of the information listed in paragraph (b)(1)(i) of this section, other reliable data sources that may be used include: FSA Farm Programs (formerly Agriculture Stabilization and Conservation Service) actual yield records and county or State averages.

(iii) This paragraph applies when an accurate projection cannot be made because the individual's production history in any or all of the previous 5 years has been substantially affected by a disaster that has been declared by the President or designated by the Secretary of Agriculture. This paragraph also applies to those individuals who would have had a qualifying physical or production loss, as defined in § 1945.154(a), from such a disaster, but who were not located in a designated or declared disaster area.

(A) If the individual's disaster years yields are less than the county average yields, county average yields will be used for those years. If county average

yields are not available, State average yields will be used.

(B) In calculating a baseline average yield, the individual may exclude the production year with the lowest actual or county average yield, providing the individual's yields were affected by disasters during at least 2 of the 5 years.

(2) Unit prices for agricultural commodities as published in the State supplement will generally be used. However, regional or county unit prices may be used when there are transportation costs or other significant factors that cause a difference in commodity prices within the State. Individuals who can provide reliable evidence that they will receive a premium price for a commodity will be allowed to use the higher price for farm planning. The determination of disaster years will be based on the 5-year history of disaster declarations or designations for all counties contained in the State supplement.

(3) When the Agency official and individual revise the farm business plan, the plan will be signed and initialed by both parties. Form FmHA 1962–1 (available in any Agency office) will be revised whenever significant changes occur during the year that will affect repayment ability. It is the individual's responsibility to notify the Agency of any necessary changes. If the changes would result in a major change in the operation, a completely new farm business plan must be developed. The individual and Agency official will initial and date revisions to the Form FmHA 1962–1.

(4) If the borrower and Agency cannot reach an agreement on revisions to the farm plan and an adverse decision results, the borrower may appeal. During an appeal, the Agency will make releases of normal income security for essential family living and farm operating expenses in accordance with § 1962.17. If the borrower refuses to execute Form FmHA 1962–1 as finally determined by the Agency after an appeal, the account will be serviced under § 1962.18. If the borrower does not appeal, the planned releases documented on Form FmHA 1962–1 are binding.

§ 1924.57 [Reserved].

§ 1924.58 Recordkeeping.

(a) All borrowers must have a recordkeeping system, which must be documented as part of the assessment under § 1924.55.

(b) The selected recordkeeping system must provide information similar to that contained in Forms FmHA 431–2, FmHA 432–1, ''Farm Family Record Book,'' and FmHA 432–2, ''Five Year Inventory Record.'' The recordkeeping system must enable borrowers to make informed management decisions and allow the Agency to render loan making and servicing decisions in accordance with Agency program regulations.

(c) Borrowers must maintain accurate records and submit financial information to the Agency when required. Failure to do so will result in the borrower's ineligibility for future Agency financing and loan servicing and may result in acceleration and collection action.

§ 1924.59 Supervision.

The Agency's supervision is based on the information and evaluation resulting from the assessment of the operation. The borrower is required to:

(a) Cooperate with the Agency and comply with all supervisory agreements, farm plans, and all other loan-related requirements.

(b) Promptly notify the Agency of any significant change in the business or family expenses or the development of problem situations.

(c) Maintain and protect the collateral for Agency loans and promptly report to the Agency any losses or other significant changes in the collateral.

(d) Complete any training required by § 1924.74.

§ 1924.60 Nonfarm enterprises.

A nonfarm enterprise is any business enterprise which supplements farm income by providing goods or services for which there is a need and a reasonably reliable market. The same general policies covered in this subpart for giving management assistance to an applicant or borrower on farm loans will be followed in dealing with an applicant or borrower on nonfarm enterprise loans. The appropriate plans and record book will be used for the nonfarm enterprise. The borrower responsibilities in § 1924.59 (a) also apply to nonfarm enterprises.

§§ 1924.61 through 1924.73 [Removed and Reserved.]

14. In part 1924 §§ 1924.61 through 1924.73 are removed and reserved.

§ 1924.74 [Amended]

15. Section 1924.74 is amended by:

a. Removing all references to ''FmHA or its successor agency under Public Law 103–354'' and adding the word ''Agency,'' it its place;

b. Removing the words ''Farmer Programs'' and adding the words ''Farm Credit Programs'' in its place; and

c. Removing the phrase ''Form FmHA or its successor agency under Public Law 103–354'' wherever it appears and adding the words ''Form FmHA'' in its place.

16. Section 1924.74 is amended by:

a. removing the ninth and twelfth sentences of introductory paragraph (b)(1) and the second sentence of paragraph (b)(1)(i);

b. removing in the eighth sentence of paragraph (b)(1) the phrase ''Form FmHA or its successor agency under Public Law 103–354 1924–23, ''

c. removing the words ''County Committee,'' ''Committee,'' in paragraphs (b)(1), (b)(1)(i), (b)(1)(ii) and (b)(2) and adding the word ''Agency'' in their place; and

d. removing the words ''County Committee's'' in paragraph (b)(3), introductory text, and paragraph (b)(4) and adding the words ''the Agency's'' in their place.

17. Section 1924.100 is revised to read as follows:

§ 1924.100 OMB control number.

The reporting and recordkeeping requirements contained in this regulation have been approved by the Office of Management and Budget (OMB) and have been assigned OMB control number 0560–0154.

18. Exhibit A is amended by redesignating all text following the closure ''County Supervisor'' as attachment 1 to exhibit A; removing all references to ''FmHA or its successor agency under Public Law 103–354'' and adding the word ''Agency'' in its place; by removing the references ''Form 1962–1'' and adding ''Form FmHA 1962–1'' in its place; and revising the first paragraph of redesignated attachment 1 to read as follows:

Exhibit A—Letter to Borrower Regarding Releases of Farm Income To Pay Family Living and Farm Operating Expenses

* * * * *

Attachment 1 to Exhibit A

Periodically, you will be asked to complete Form FmHA 1962–1, ''Agreement for the Use of Proceeds/ Release of Chattel Security,'' which will document the agreement between you and the Agency as to how proceeds from the sale of chattel property which serves as security for your Agency loans will be released. You will also need to list those buyers to whom you plan to sell your farm products. This plan will give you and the Agency a clear idea of what income you expect from your operation and how those proceeds will be used. The plan will set forth the amount of money required for paying essential family living, farm operating expenses, and debt service payments. You and the

Agency must agree on how much money will be released from your crop proceeds. Such releases must be in accordance with Agency regulations.
* * * * *

PART 1941—OPERATING LOANS

19. The authority citation for part 1941 is revised to read as follows:

Authority: 5 U.S.C. 301; 7 U.S.C. 1989.

Subpart A—Operating Loan Policies, Procedures, and Authorizations

§ 1941.1 [Amended]

20. Section 1941.1 is amended by removing the words ''Farmers Home Administration (FmHA)'' and adding the words ''Farm Service Agency (FSA)'' in its place in the fourth sentence and removing ''FmHA'' and adding the word ''Agency'' in its place.

§ 1941.4 [Amended]

21. Section 1941.4 is amended by adding the definition for ''Agency'' after the definition for ''Additional security.''
* * * * *

Agency. The Farm Service Agency, its county and State committees and their personnel, and any successor agency.
* * * * *

§ 1941.15 [Amended]

22. Section 1941.15 paragraph (e) is amended by:

a. removing the reference to ''§ 1924.57'' and adding ''§ 1924.56'' in its place;

b. removing the phrase ''for County Committee review'';

c. removing the phrase ''FmHA or its successor agency under Public Law 103–354'' in paragraphs (c), (e)(2), (f)(3), (j), and the heading of paragraph (i) and adding the word ''Agency'' in its place;

d. by removing the words ''FmHA or its successor agency under Public Law 103–354's'' in paragraphs (e)(3) and (j) and adding the words ''the Agency's'' in its place.

23. Section 1941.15 is amended by:

a. removing the second sentence in paragraph (a);

b. removing the phrase ''FmHA or its successor agency under Public Law 103–354-assisted'' in the first sentence of paragraph (a) and paragraph (h)(2) introductory text;

c. removing the phrase ''FmHA or its successor agency under Public Law 103–354 regulations setting forth'' in the last sentence of paragraph (f)(2);

d. removing the words ''County Committee'' and adding the word ''Agency'' in its place in paragraph (h)(1); and

e. removing the phrase ''subpart B of part 1900 of this chapter'' and adding ''7 CFR part 780'' in its place in paragraph (h)(3); and

f. revising paragraph (k) to read as follows:

§ 1941.15 Special beginning farmer or rancher OL loan assistance.

* * * * *

(k) *Agency certification*. A special beginning farmer OL application will only be considered after the applicant submits a complete 5-year plan of operation and a projection of the financial status of the operation as set forth in paragraph (e) of this section. In addition to the requirements of § 1941.30, the following conditions apply:

(1) Agency certifications of eligibility under paragraph (b) of this section are effective throughout the commitment period.

(2) For subsequent loan requests during the commitment period, the Agency will certify as to the applicant meeting the eligibility requirements for the regular direct or guaranteed OL loan programs, as appropriate. Such certification is unnecessary if a 5-year eligibility certification has not yet expired unless the County Supervisor has determined that the applicant's situation has changed such that the eligibility determination would potentially be affected. If recertification is rejected, no subsequent loan will be made under the commitment and the commitment will be revoked in accordance with paragraph (h) of this section.

§ 1941.16 [Amended]

24. Section 1941.16 paragraph (k) is amended by removing the words ''Agricultural Stabilization and Conservation Service (ASCS)'' and adding the words ''FSA Farm Programs (formerly Agricultural Stabilization and Conservation Service)'' in its place.

§ 1941.18 [Amended]

25. Section 1941.18 is amended:

a. In paragraph (a), introductory text, by removing ''FmHA'' and adding the words ''the Agency'' in its place and

b. In paragraph (a)(2), by removing the reference to ''§ 1924.60'' and adding ''§ 1924.55'' in its place.

§ 1941.19 [Amended]

26. Section 1941.19 paragraph (f)(1) is amended:

a. by removing the phrase ''FmHA or its successor agency under Public Law 103–354 for any other farmer programs'' and adding the phrase ''the Agency for any other farm credit programs'' in its place and

b. by removing paragraphs (g) through (j).

§ 1941.30 [Removed and Reserved]

27. In part 1941 § 1941.30 is removed and reserved.

§ 1941.33 [Amended]

28. Section 1941.33 is amended:

a. by removing the words ''County Committee'' in paragraph (b)(1)(i) and adding the word ''Agency'' in its place,

b. by removing paragraph (b)(1)(ii),

c. by redesignating paragraphs (b)(1)(iii) through (vii) as (b)(1) (ii) through (vi), respectively;

d. by removing the second reference to ''FmHA'' in paragraph (b)(2)(i), and

e. by removing the words ''(see subpart B of part 1900 of this chapter)'' from paragraph (c)(2).

PART 1943—FARM OWNERSHIP, SOIL AND WATER AND RECREATION

29. The authority citation for part 1943 is revised to read as follows:

Authority: 5 U.S.C. 301; and 7 U.S.C. 1989.

Subpart A—Direct Farm Ownership Loan Policies, Procedures and Authorizations

§ 1943.1 [Amended]

30. Section 1943.1 is amended by removing the words ''Farmers Home Administration (FmHA)'' and adding the words ''Farm Service Agency (FSA)'' in its place and § 1943.2 is amended by removing ''FmHA'' and adding the word ''Agency'' in its place.

§ 1943.4 [Amended]

31. Section 1943.4 is amended in the definition of *primary security* by removing ''and/or'' and adding ''and'' in its place, and also by adding the following definition after the definition of *additional security*.
* * * * *

Agency. The Farm Service Agency, its county and State committees and their personnel, and any successor agency.
* * * * *

§ 1943.18 [Amended]

32. Section 1943.18(b)(3) is amended by removing the reference to ''§ 1924.60'' and adding ''§ 1924.55'' in its place.

§ 1943.29 [Amended]

33. Section 1943.29 (c) is amended by removing the references to ''FmHA'' and adding the words ''the Agency'' in its place.

§§ 1943.30 and 1943.32 [Removed and Reserved]

34. In part 1943 §§ 1943.30 and 1943.32 are removed and reserved.

§ 1943.33 [Amended]

35. Section 1943.33 is amended by:

a. removing and reserving paragraph (b)(2);

b. removing paragraph (c);

c. removing the words ''County Committee'' in paragraph (b)(1)(i) and adding the word ''Agency'' in its place; and

d. removing paragraph (b)(1)(ii); and redesignating paragraphs (b)(1) (iii) through (vii) as (b)(1) (ii) through (vi) respectively.

Subpart B—Direct Soil and Water Loan Policies, Procedures and Authorizations

§§ 1943.80 and 1943.82 [Removed and Reserved]

36. In part 1943 §§ 1943.80 and 1943.82 are removed and reserved.

§ 1943.83 [Amended]

37. Section 1943.83 is amended by:

a. removing the words ''County Committee'' in paragraph (b)(1)(i) and adding the word ''Agency'' in its place;

b. removing paragraph (b)(1)(ii); and redesignating paragraphs (b)(1) (iii) through (vii) as paragraphs (b)(1)(ii) through (vi) respectively; and

c. removing and reserving paragraph (b)(2); and removing paragraph (c).

PART 1945—EMERGENCY

38. The authority citation for part 1945 is revised to read as follows:

Authority: 5 U.S.C. 301; 7 U.S.C. 1989; and 42 U.S.C. 1980.

Subpart D—Emergency Loan Policies, Procedures and Authorizations

§§ 1945.151 and 1945.152 [Amended]

39. Sections 1945.151 and 1945.152 are amended by removing the words ''Farmers Home Administration (FmHA)'' and adding the words ''Farm Service Agency (FSA)'' in its place and by removing ''FmHA'' and adding the word ''Agency'' in its place.

§ 1945.154 [Amended]

40. Section 1945.154 (a) is amended in the definition of *Feasible Plan* by removing words ''§ 1924.57(c)(5) of'' and also by adding the following definition after the definition of *Additional security*.

* * * * *

Agency. The Farm Service Agency, its county and State committees and their personnel, and any successor agency.

* * * * *

41. Section 1945.163 is amended by:

a. removing all references to ''Form FmHA or its successor agency under Public Law 103–354 and adding the words ''Form FmHA'' in their place;

b. removing the reference to ''FmHA'' in the last sentence of introductory text; and adding the words ''the Agency'' in its place; and

c. by removing and reserving paragraph (a)(2)(ii) and revising paragraph (a)(1) to read as follows:

§ 1945.163 Determining qualifying losses, eligibility for EM loan(s) and the maximum amount of each.

* * * * *

(a) * * *

(1) The normal year's production will be established by eliminating the poorest year of the 5-year production history immediately preceding the disaster year and averaging the remaining 4 years' production. The applicant must select the year to be eliminated. The year selected to be eliminated must be the same year for all farm enterprises (i.e., all crops, livestock, and livestock products), which constituted a part of the applicant's farming operation during that year. Applicants will identify the production for each commodity that was produced on all farms operated by the applicant in the disaster year. Applicants must use the production record sources for each crop in the order of priority as follows:

(i) *The applicant's actual reliable farm records.* If actual yields are not available for all of the 5 crop years, the applicant will use a combination of actual records and other data as specified in paragraphs (a)(1) (ii) and (iii) of this section.

(ii) *FSA Farm Programs (formerly ASCS) ''actual yields.''* When this production record source is used, the applicant must obtain the information and submit it with the application. The disaster year actual yield will be used as the yield for those years for which the applicant has no production records to determine the normal year's yields.

(iii) *The county or State average yields.* These average yields are located in the State supplement. However, these production figures can be substituted only when an applicant has insufficient records for certain commodities and years.

(iv) *State Director determination.* When an applicant's production loss is on new land being developed, or to young perennial crops such as fruits and nuts, which have not reached their mature production potential, the Agency will establish the normal yields to be used.

* * * * *

§ 1945.166 [Amended]

42. Section 1945.166 is amended by removing ''FmHA'' in the last sentence of paragraph (c)(4) and adding the word ''Agency'' in its place.

§ 1945.167 [Amended]

43. Section 1945.167 is amended by removing paragraph (g); removing paragraph (h); redesignating paragraphs (i) through (k) as (h) through (j), and removing ''FmHA'' wherever it appears in redesignated paragraph (h) and adding the word ''Agency'' in its place.

44. Section 1945.167 is amended by:

a. removing the words ''crop(s)'' and ''disaster(s)'' in paragraph (a) and adding the words ''crop'' and ''disaster'' in their place respectively;

b. removing the words ''FmHA or its successor agency under Public Law 103–354'' in the heading of paragraph (b) and adding the word ''Agency'' in its place; and removing the words ''FmHA or its successor agency under Public Law 103–354 farmer programs'' in paragraph (b) and adding the words ''Farm Credit Programs'' in its place;

c. removing the word ''purpose(s)'' in the heading of paragraph (c) and adding the word ''purposes'' in its place; removing the word ''operation(s)'' in paragraph (c) and adding the word ''operation'' in its place.

§ 1945.168 [Amended]

45. Section 1945.168 is amended:

a. by removing ''FmHA'' in the first sentence of paragraph (a) and adding the words ''the Agency'' in its place; and

b. by removing the words ''loan(s)'', ''reason(s)'' and ''lien(s) in paragraphs (b)(1)(i) and (ii) and adding the words ''loans'', ''reasons'' and ''lien'' in their place, respectively.

§ 1945.169 [Amended]

46. Section 1945.169 is amended by removing and reserving paragraphs (n), (o), and removing (p)(3), and (p)(4).

§ 1945.173 [Amended]

47. Section 1945.173 is amended by removing ''FmHA'' in paragraph (b)(2)(ii) and adding the word ''Agency'' in its place.

§§ 1945.180 and 1945.182 [Removed and Reserved]

48. In part 1945 §§ 1945.180 and 1945.182 are removed and reserved.

§ 1945.183 [Amended]

49. Section 1945.183 is amended by removing and reserving paragraphs (a)(1) through (3), (a)(4)(i) and (ii); and removing (c) through (e).

50. Section 1945.183 is amended:

a. by removing the words ''County Committee'' in paragraph (b) introductory text, and paragraph (b)(1) and adding the word ''Agency'' in its place;

b. by removing the phrase ''FmHA or its successor agency under Public Law 103–354'' in paragraphs (a)(4)(iii), (b)(7)

and (b)(8) and adding the word ''Agency'' in its place;

c. by removing the word ''loan(s)'' in paragraphs (b)(4) and (b)(8) and adding the word ''loan'' in its place;

d. by removing the word ''certification(s)'' in paragraph (b)(6) and adding the word ''certifications'' in its place; and

e. by removing the words ''Form FmHA or its successor agency under Public Law 103–354'' wherever it appears and adding the words ''Form FmHA'' in its place.

PART 1951—SERVICING AND COLLECTIONS

51. The authority citation for part 1951 is revised to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 1480.

Subpart F—Analyzing Credit Needs and Graduation of Borrowers

52. Sections 1951.251 through 1951.300 are revised to read as follows:

§ 1951.251 Purpose.

This subpart prescribes the policies to be followed when analyzing a direct borrower's needs for continued Agency supervision, further credit, and graduation. All loan accounts will be reviewed for graduation in accordance with this subpart, with the exception of Guaranteed, Watershed, Resource Conservation and Development, Rural Development Loan Funds, and Rural Rental Housing loans made to build or acquire new units pursuant to contracts entered into on or after December 15, 1989, and Intermediary Relending Program loans. The term ''Agency'' used in this subpart refers to the Farm Service Agency (FSA) including its county and state committees and their personnel), Rural Utilities Service (RUS), Rural Housing Service (RHS), or Rural Business-Cooperative Service (RBS), depending upon the loan program discussed herein.

§ 1951.252 Definitions.

Commercial classified. The Agency's highest quality Farm Credit Programs (FCP) accounts. The financial condition of the borrowers is strong enough to enable them to absorb the normal adversities of agricultural production and marketing. There is ample security for all loans, there is sufficient cash flow to meet the expenses of the agricultural enterprise and the financial needs of the family, and to service debts. The account is of such quality that commercial lenders would likely view the loans as a profitable investment.

Farm Credit Programs (FCP) loans. FSA Farm Ownership (FO), Operating (OL), Soil and Water (SW), Recreation (RL), Emergency (EM), Economic Emergency (EE), Economic Opportunity (EO), Special Livestock (SL), Softwood Timber (ST) loans, and Rural Housing loans for farm service buildings (RHF).

Graduation, FCP. The payment in full of all FCP loans or all FCP loans of one type (i.e., all loans made for chattel purposes or all loans made for real estate purposes) by refinancing with other credit sources either with or without an Agency loan guarantee. A loan made for both chattel and real estate purposes, for example an EM loan, will be classified according to how the majority of the loan's funds were expended. Borrowers must continue with their farming operations to be considered as graduated.

Graduation, other programs. The payment in full of any direct loan for Community and Business Programs, and all direct loans for housing programs, before maturity by refinancing with other credit sources. Graduated housing borrowers must continue to hold title to the property. Graduation, for other than FCP, does not include credit which is guaranteed by the United States.

Prospectus, FCP. Consists of a transmittal letter with a current balance sheet and projected year's budget attached. The applicant's or borrower's name and address need not be withheld from the lender. The prospectus is used to determine lender interest in financing or refinancing specific Agency direct loan applicants and borrowers. The prospectus will provide information regarding the availability of an Agency loan guarantee and interest assistance.

Reasonable rates and terms. Those commercial rates and terms which borrowers are expected to meet when borrowing for similar purposes and similar periods of time. The ''similar periods of time'' of available commercial loans will be measured against, but need not be the same as, the remaining or original term of the loan. In the case of Multi-Family Housing (MFH) loans, ''reasonable rates and terms'' would be considered to mean financing that would allow the units to be offered to eligible tenants at rates consistent with other multi-family housing.

Servicing official. The district or county office official responsible for the immediate servicing functions of the borrower.

Standard classified. These loan accounts are fully acceptable by Agency standards. Loan risk and potential loan servicing costs are higher than would be acceptable to other lenders, but all loans are adequately secured. Repayment ability is adequate, and there is a high probability that all loans will be repaid as scheduled and in full.

§ 1951.253 Objectives.

(a) [Reserved]

(b) Borrowers must graduate to other credit at reasonable rates and terms when they are able to do so.

(c) If a borrower refuses to graduate, the account will be liquidated under the following conditions:

(1) The borrower has the legal capacity and financial ability to obtain other credit.

(2) Other credit is available from a commercial lender at reasonable rates and terms. In the case of Labor Housing (LH), Rural Rental Housing (RRH), and Rural Cooperative Housing (RCH) Programs, reasonable rates and terms must also permit the borrowers to continue providing housing for low and moderate income persons at rental rates tenants can afford considering the loss of any subsidy which will be canceled when the loan is paid in full.

(d) The Agency will enforce borrower graduation.

§ 1951.254 [Reserved]

§ 1951.255 Nondiscrimination.

All loan servicing actions described in this subpart will be conducted without regard to race, color, religion, sex, familial status, national origin, age, or physical or mental handicap.

§§ 1951.256—1951.261 [Reserved]

§ 1951.262 Farm Credit Programs—graduation of borrowers.

(a) [Reserved].

(b) [Reserved].

(c) [Reserved].

(d) [Reserved].

(e) *Graduation candidates.* Borrowers who are classified ''commercial'' or ''standard'' are graduation candidates. At least every 2 years, all borrowers who have a current classification of commercial or standard must submit a year-end balance sheet, actual financial performance information for the most recent year, and a projected budget for the current year to enable the Agency to reclassify their status and determine their ability to graduate.

(f) *Sending prospectus information to lenders.* (1) The Agency will distribute a borrower's prospectus to local lenders for possible refinancing only with the borrower's written permission. If more than one lender indicates an interest in providing credit, the borrower has the right to select a lender.

(2) If any borrower does not consent to the Agency contacting lenders directly on their behalf, the borrower must make formal application to at least

two local lenders who typically finance operations similar to that of the borrower. The borrower is responsible for any application fees. Letters of denial or rejection from lenders without formal application being made will not be accepted by the Agency. The borrower has 60 days from the date the borrower receives the prospectus information to make application and receive a response from lenders. For good cause, the borrower may be granted a reasonable amount of additional time by the Agency.

§ 1951.263 Graduation of non-Farm Credit programs borrowers.

(a) [Reserved].

(b) [Reserved].

(c) *The thorough review.* Borrowers are required to supply such financial information as the Agency deems necessary to determine whether they are able to graduate to other credit. At a minimum, the financial statements requested from the borrower must include a balance sheet and a statement of income and expenses. Ordinarily, the financial statements will be those normally required at the end of the particular borrower's fiscal year. For borrowers who are not requested to furnish audited financial statements, the balance sheet and statement of income and expenses may be of the borrower's own format if the borrower's financial situation is accurately reflected. The borrower has 60 days for group type loans and 30 days for individual type loans to supply the financial information requested.

(d) [Reserved].

(e) *Requesting the borrower to graduate.* (1) The Agency will send written notice to borrowers found able to graduate requesting them to graduate. The borrower must seek a loan only in the amount necessary to repay the unpaid balance.

(2) Borrowers must provide evidence of their ability or inability to graduate within 30 days for RH borrowers, and 90 days for group type borrowers, after the date of the request. The Agency may allow additional time for good cause, for example when a borrower expects to receive income in the near future for the payment of accounts which would substantially reduce the amount required for refinancing, or when a borrower is a public body and must issue bonds to accomplish graduation.

(3) If a borrower is unable to graduate the full amount of the loan, the borrower must furnish evidence to the Agency, showing:

(i) The names of other lenders contacted;

(ii) The amount of loan requested by the borrower and the amount, if any, offered by the lenders;

(iii) The rates and terms offered by the lenders or the specific reasons why other credit is not available; and

(iv) The purpose of the loan request.

(4) The difference in interest rates between the Agency and other lenders will not be sufficient reason for failure to graduate if the other credit is available at rates and terms which the borrower can reasonably be expected to pay. An exception is made where there is an interest rate ceiling imposed by Federal law or contained in the note or mortgage.

(5) The Agency will notify the borrower in writing if it determines that the borrower can graduate. The borrower must take positive steps to graduate within 15 days for individual loans and 60 days for group loans from such notice to avoid legal action. The servicing official may grant a longer period where warranted.

§ 1951.264 Action when borrower fails to cooperate, respond or graduate.

(a) When borrowers with other than FCP loans fail to:

(1) Provide information following receipt of both FmHA Guide Letters 1951–1 and 1951–2 (available in any Agency office), or letters of similar format, they are in default of the terms of their security instruments. The approval official may, when appropriate, accelerate the account based on the borrower's failure to perform as required by this subpart and the loan and security instruments.

(2) Apply for or accept other credit following receipt of both FmHA Guide Letters 1951–F–5 and 1951–6 (available in any Agency office), or letters of similar format, they are in default under the graduation requirement of their security instruments. If the Agency determines the borrower is able to graduate, foreclosure action will be initiated in accordance with § 1955.15(d)(2)(ii). If the borrower's account is accelerated, the borrower may appeal the decision.

(b) If an FCP borrower fails to cooperate after a lender expresses a willingness to consider refinancing the Agency loan, the account will be referred for legal action.

§ 1951.265 Application for subsequent loan, subordination, or consent to additional indebtedness from a borrower who has been requested to graduate.

(a) Any borrower who appears to meet the local commercial lending standards, taking into consideration the Agency's loan guarantee program, will not be considered for a subsequent loan, subordination, or consent to additional indebtedness until the borrower's ability or inability to graduate has been confirmed. An exception may be made where the proposed action is needed to alleviate an emergency situation, such as meeting applicable health or sanitary standards which require immediate attention.

(b) If the borrower has been requested to graduate and has also been denied a request for a subsequent loan, subordination, or consent to additional indebtedness, the borrower may appeal both issues.

§ 1951.266 Special requirements for MFH borrowers.

All requirements of subpart E of part 1965 must be met prior to graduation and acceptance of the full payment from an MFH borrower.

§§ 1951.267–1951.299 [Reserved]

§ 1951.300 OMB control number.

The reporting requirements contained in this regulation have been approved by the Office of Management and Budget (OMB) and have been assigned OMB control number 0575–0093.

Exhibit A of Subpart F—[Removed and Reserved]

53. Exhibit A of subpart F is removed and reserved.

Subpart S—Farmer Program Account Servicing Policies

54. Section 1951.906 is amended by revising the definitions of ''Feasible plan,'' ''Financially distressed,'' and ''Good faith'' to read as follows:

§ 1951.906 Definitions.

* * * * *

Feasible plan. A feasible plan is a plan based upon the applicant's or borrower's actual records that show the farming operation's actual income, production and expenses. Income tax returns and supporting documents (hereafter called income tax records) must be submitted to verify the actual records. The records, including income tax records, must be for the most recent 5-year period or if the borrower has been farming less than 5 years, the records for the period which the borrower has farmed. For borrowers who have been farming for less than 5 years, the borrower's actual records will be used along with other available records in the order listed in § 1924.56 to complete a 5-year history. Future production yields will be based on a 5-year average of the most recent past 5 years' actual production yields.

Borrowers that have yields affected by disasters in at least 2 of the 5 most recent years' actual production may exclude the crop year with the lowest actual yield. In accordance with § 1924.56, if the applicant's remaining disaster year's yields are less than the county average yield and the borrower's yields were affected by the disaster, county average yields will be used for that year. If county average yields are not available, State average yields will be used. These records will be used along with realistic anticipated prices, including any planned farm program payments, to determine that the income from the farming operation and any reliable off-farm income, will provide the income necessary for an applicant or borrower to at least be able to:

(1) Pay all operating expenses and all taxes which are due during the projected farm business accounting period.

* * * * *

(3) Meet up to 105 percent, but not less than 100 percent, of the scheduled payments on all debts, except as provided in § 1941.14 for annual production loans or subordinations made to a delinquent borrower submitting a ''NEW APPLICATION.'' The Agency will assume that a borrower needs up to 105 percent of the scheduled payments on all the debts for the business accounting period in order to meet the obligations and continue farming. However, this will not prohibit a borrower from receiving debt restructuring because the projected income is less than 105 percent of the scheduled payments. In no case will a borrower receive restructuring if projected income is less than 100 percent of scheduled payments.

* * * * *

Financially distressed. A financially distressed borrower is one who will not be able to make payments as planned for the current or next business accounting period. Borrowers will also be considered financially distressed if the borrower will not be able to project a feasible plan of operation for the next business accounting period.

* * * * *

Good faith. An eligibility requirement for Primary Loan Servicing including Net Recovery Buyout, and Leaseback/Buyback. A borrower is considered to have acted in ''good faith'' if the borrower has demonstrated honesty and sincerity in carrying out the agreements on Form FmHA 1962–1 (available in any Agency office) and any other written agreements with the Agency. Findings of a lack of good faith will be based on violations within the borrower's control. These actions will demonstrate the borrower's intent to violate written agreements with the Agency. The Agency must substantiate any allegations of fraud, waste, or conversion with a written legal opinion by the Office of the General Counsel (OGC) when such allegations are used to deny a servicing request. A borrower will not be considered to lack good faith if the sole basis for such determination was the disposition of normal income security, as defined in § 1962.4, prior to October 14, 1988 without the Agency's consent and the borrower demonstrates that the proceeds were used to pay essential family living and farm operating expenses that the Agency could have approved according to § 1962.17.

* * * * *

§ 1951.909 [Amended]

55. Section 1951.909 is amended:

a. by removing the reference to ''§ 1924.60 of subpart B of part 1924 of this chapter'' in paragraph (e)(3)(vii) and adding the reference ''§ 1924.55,'' in its place and;

b. by removing the reference ''as set forth in subpart B of part 1900 of this chapter'' in paragraph (e)(3)(vii).

56. Section 1951.909 is amended:

a. by removing the phrase ''FmHA or its successor agency under Public Law 103–354'' in the heading of paragraph (e)(4) and in paragraph (e)(4)(xi) and adding the word ''Agency'' in its place; and

b. by removing and reserving paragraphs (e)(3)(vi)(B) and (C).

PART 1955—PROPERTY MANAGEMENT

57. The authority citation for part 1955 is revised to read as follows:

Authority: 5 U.S.C. 301; 7 U.S.C. 1989; 42 U.S.C. 1480.

Subpart B—Management of Property

§ 1955.66 [Amended]

58. Section 1955.66 is amended:

a. by removing the words ''Farmer Program loans'' in paragraphs (a)(2)(iii)(A) and adding the words ''Farm Credit Programs loans'' in their place;

b. by removing the reference ''§ 1924.27 of'' in paragraph (a)(2)(iii)(B);

c. by removing the phrase ''FmHA or its successor agency under Public Law 103–354'' in the third sentence of the introductory text and paragraphs (a)(1) and (a)(2)(iii)(C) and adding the words ''the Agency'' in its place; and

d. by removing the words ''Agricultural Stabilization and Conservation Service (ASCS)'' in paragraph (a)(2)(iii)(D) and adding the words ''the local FSA Farm Programs (formerly ASCS)'' in its place.

PART 1962—PERSONAL PROPERTY

59. The authority citation for part 1962 is revised to read as follows:

Authority: 5 U.S.C. 301; 7 U.S.C. 1989; 42 U.S.C. 1480.

Subpart A—Servicing and Liquidation of Chattel Security

§ 1962.5 [Removed and Reserved]

60. In part 1962 § 1962.5 is removed and reserved.

61. Section 1962.6 is revised to read as follows:

§ 1962.6 Liens and assignments on chattel property.

(a) *Chattel property not covered by Agency lien.* (1) When additional chattel property not presently covered by an Agency lien is available and needed to protect the Government's interest, the County Supervisor will obtain one or more of the following:

(i) A lien on such property.

(ii) An assignment of the proceeds from the sale of agricultural products when such products are not covered by the lien instruments.

(iii) An assignment of other income, including FSA Farm Programs (formerly ASCS) payments.

(2) When a current loan is not being made to a borrower, a crop lien will be taken as additional security when the County Supervisor determines in individual cases that it is needed to protect the Government's interests. However, a crop lien will not be taken as additional security for Farm Ownership (FO), Rural Housing (RH), Labor Housing (LH), and Soil and Water (SW) loans. When a new security agreement or chattel mortgage is taken, all existing security items will be described on it.

(b) [Reserved]

(c) *Assignments of upland cotton, rice, wheat and feed grain payments.* Borrowers may assign FSA Farm Programs (formerly ASCS) payments under upland cotton, rice, wheat and feed grain programs.

(1) *Obtaining assignments.* Assignments will be obtained as follows:

(i) Only when it appears necessary to collect operating-type loans.

(ii) Only for the crop year for which operating-type loans are made, and

(iii) For only the amount anticipated for payments as indicated on Form FmHA 1962–1, ''Agreement for the Use of Proceeds/Release of Chattel

Security,'' of the applicable upland cotton, rice, wheat and feed grain programs.

(2) *Selecting counties.* The County Supervisor then will:

(i) Determine, at the time of loan processing for indebted borrowers and new applicants, who must give assignments and obtain them no later than loan closing. Special efforts will be made to obtain the bulk of assignments before the sign-up period for enrolling in the annual Feed Grain and Wheat set aside programs.

(ii) Obtain assignments from selected borrowers on Form ASCS–36, ''Assignments of Payment,'' which will be obtained from FSA Farm Programs.

(3) *Releasing assignments and handling checks.* (i) The County Supervisor will inform FSA Farm Programs that releasing its assignment whenever a borrower pays the amount due for the year on the operating-type loan debt or pays the debt in full.

(ii) Checks obtained as a result of an assignment will be made only to the Agency, and the proceeds used as indicated on Form FmHA 1962–1.

§ 1962.8 [Amended]

62. Section 1962.8 is amended by removing and reserving paragraphs (a) and (b).

§ 1962.9 and 1962.12 [Removed and Reserved]

63. In part 1962 §§ 1962.9 and 1962.12 are removed and reserved.

64. Section 1962.13 is revised to read as follows:

§ 1962.13 Notification to potential purchasers.

(a) In States without a Central Filing System (CFS), all Farm Credit Programs borrowers prior to loan closing or prior to any servicing actions which require taking a lien on farm products, such as crops or livestock, must provide the names and addresses of potential purchasers. A written notice will be sent by the Agency, certified mail, return receipt requested, to these potential purchasers to protect the Government's security interest.

(1) The name and address of the debtor, with signature.

(2) The name and address of any secured party.

(3) The Social Security number or tax ID number of the debtor.

(4) A description of the farm products given as security by the debtor, including the amount of such products where applicable, the crop year, the county in which the products are located, and a reasonable description of the farm products.

(5) Any payment obligation imposed on the potential purchaser by the secured party as a condition for waiver or release of lien. The original or a copy of the written notice also must be sent to the purchaser within 1 year before the sale of the farm products. The written notice will lapse on either the expiration period of the Financing Statement or the transmission of a letter signed by the County Supervisor and showing that the statement has lapsed or the borrower has performed all obligations to the Agency.

(b) Lists of borrowers whose chattels or crops are subject to an Agency lien may be made available, upon request, to business firms in a trade area, such as sale barns and warehouses, that buy chattels or crops or sell them for a commission. These lists will exclude those borrowers whose only crops for sale require FSA Farm Programs (formerly ASCS) marketing cards. The list is furnished only as a convenience and may be incomplete or inaccurate as of any particular date.

(1) [Reserved]

(2) [Reserved]

65. In § 1962.14 all references to ''FmHA or its successor agency under Public Law 103–354'' are removed and the words ''the Agency'' are added in their place.

66. Section 1962.16, introductory text is added and paragraph (a) is revised to read as follows:

§ 1962.16 Accounting by the borrower.

The Agency will maintain a current record of each borrower's security. Whenever an inspection is performed, the borrower must advise the Agency of any changes in the security and will complete and sign Form FmHA 1962–1 in accordance with § 1924.56 if it has not been previously completed for the year.

(a) *Agency responsibilities.* Chattel security will be inspected annually except in cases where the Agency official has justified in assessment or analysis review that no undue risk exists. An FO borrower who has been current with the Agency and who has provided chattels as additional security is an example of a case where an inspection may not be needed. All inspections will be recorded in the running record of the borrower's file. More frequent inspections should be made for delinquent borrowers or borrowers that have been indebted for less then 1 full crop year. The Agency official will discuss the provisions of §§ 1962.17 and 1962.18 and assist the borrower in completing the form. If a borrower does not plan to dispose of any chattel security, the form should be completed to show this and should be signed. When the Agency official has other contacts with the borrower, the official should also check for dispositions and acquisitions of security. Changes will be recorded on the form, dated and initialed by the borrower and the agency official. The purpose of all inspections is to:

(1) Verify that the borrower possesses all the security,

(2) Determine security is properly maintained, and

(3) Supplement security instruments.

* * * * *

67. Section 1962.17, paragraph (a), is revised to read as follows:

§ 1962.17 Disposal of chattel security, use of proceeds and release of lien.

(a) *General.* (1) The borrower must account for all security. When the borrower sells security, the property and proceeds remain subject to the Agency's lien until the lien is released. All checks, drafts, or money orders which the borrower receives for the sale of collateral listed on Form FmHA 1962–1 (available in any Agency office) must be payable to both the borrower and the Agency unless all Agency loan installments for the period of the form have been paid including any past-due installments. If the borrower disposes of collateral or uses the proceeds in a way not listed on Form FmHA 1962–1, the borrower will have violated the loan agreement, and the Government will not release its security interest in the collateral. Releases of sales proceeds will be terminated when the borrower's accounts are accelerated.

(2) Section 1924.56 requires that there must always be a current Form FmHA 1962–1 in the file of a borrower with a loan secured by chattels. If a borrower asks the Agency to release proceeds from the sale of chattels and there is a current Form FmHA 1962–1 in the file, the request will be approved or disapproved in accordance with paragraph (b) of this section. If the borrower's request for release is denied, the borrower must be given attachment 1 of exhibit A of subpart S of part 1951 of this chapter, a written explanation of the reasons for the denial, and the opportunity for an appeal in accordance with 7 CFR part 780. Immediately upon determining that the borrower does not have a current Form FmHA 1962–1 in the file, the County Supervisor will immediately contact the borrower to develop one.

(3) If the borrower requests a change(s) to Form FmHA 1962–1, and the County Supervisor can approve the change(s), the borrower and the County Supervisor will initial and date each

change in accordance with item (6) in the Forms Manual Insert (FMI) for Form FmHA 1962–1. The form will be marked ''Revised'' and the borrower will be notified in writing confirming that the change(s) has been approved.

* * * * *

68. Section 1962.17 is amended by:

a. removing the phrase ''or its successor agency under Public Law 103–354'' wherever it appears;

b. removing the word ''FmHA,'' except when it refers to ''Form FmHA,'' the second time it appears in paragraph (a)(1), in paragraphs (a)(2), (b)(2), (b)(2)(v), the second time it appears in paragraph (b)(2)(vii), in paragraphs (b)(2)(viii)(B), (b)(3), (b)(5), (c)(2)(i), in the first and last sentences of paragraph (d)(2)(ii), and in paragraphs (e)(1)(i) through (e)(1)(iii) and adding the words ''the Agency'' in its place;

c. removing the word ''FmHA,'' except when it refers to ''Form FmHA,'' in the first and second sentences of paragraphs (b)(1) and in paragraphs (b)(2)(iv), (b)(2)(vi), (b)(2)(vii), (c)(2), (c)(2)(ii), (c)(4), (c)(5), (d), (f) and (g) and adding the word ''Agency'' in its place;

d. removing the reference to ''1924.57(d)'' in the last sentence of paragraph (b)(5) and adding the reference ''1924.56'' in its place;

e. removing the words ''Farmer Programs'' in paragraph (c)(5) and adding the words ''Farm Credit Programs'' in its place; and

f. removing the words ''Farmers Home Administration'' in paragraph (d)(2)(ii).

* * * * *

§ 1962.34 [Amended]

69. Section 1962.34 is amended by:

a. removing paragraphs (f) through (h);

b. removing the phrase ''FmHA or its successor agency under Public Law 103–354's'' in paragraph (b)(1) and adding the words ''the Agency's'' in its place;

c. removing the phrase ''FmHA or its successor agency under Public Law 103–354'' in paragraphs (b)(2), (b)(4), and (d), and the first word at the beginning of the first sentence and the second, fourth, and fifth sentences of paragraph (b)(3) and adding the word ''Agency'' in its place;

d. removing the phrase ''Form FmHA or its successor agency under Public Law 103–354 1964–13'' in paragraph (b)(3) and adding the words ''Form FmHA 1965–13'' in its place;

e. removing the words ''Farmer Programs'' in paragraphs (b)(3) and (d) and adding the words ''Farm Credit Programs'' in its place; and

f. by revising paragraph (e) to read as follows:

§ 1962.34 Transfer of chattel security and EO property and assumption of debts.

* * * * *

(e) *Agency actions.*

(1) *Transfer to eligible applicant.* The Agency will determine the transferee's eligibility for the type of loan to be assumed.

(2) *Release from liability.* If the total outstanding debt is not assumed, the Agency must make the following determinations before it releases the transferor from personal liability:

(i) The transferor and any cosigner do not have reasonable ability to pay all or a substantial part of the balance of the debt not assumed after considering their assets and income at the time of transfer,

(ii) The transferor and any cosigner have cooperated in good faith, used due diligence to maintain the security against loss, and have otherwise fulfilled the covenants incident to the loan to the best of their ability, and

(iii) The transferee will assume a portion of the indebtedness at least equal to the present market value of the security.

* * * * *

§ 1962.40 [Amended]

70. Section 1962.40 is amended by:

a. adding the words ''subpart A of'' immediately preceding the reference ''part 1965'' in paragraph (c);

b. removing the word ''insured'' in the heading of paragraph (d) and adding the word ''direct'' in its place; removing the words ''an insured'' in the first sentence of paragraph (d) and adding the words ''a direct'' in its place; and by removing the phrase ''to FmHA or its successor agency under Public Law 103–354'' in the first sentence of paragraph (d);

c. removing the phrase ''FmHA or its successor agency under Public Law 103–354's'' in the second sentence of paragraph (d) and in paragraph (e)(1) and adding the word ''Government's'' in its place;

d. removing all references to ''FmHA or its successor agency under Public Law 103–354'' in paragraphs (e)(1)(i) and (e)(2) and adding the words ''the Agency'' in their place; and

e. removing and reserving paragraph (e)(4).

§ 1962.43 [Removed and Reserved]

71. In part 1962 § 1962.43 is removed and reserved.

§ 1962.44 [Amended]

72. Section 1962.44 is amended by removing and reserving paragraphs (a) and (c); and by removing all references to ''FmHA or its successor agency under Public Law 103–354'' in paragraph (b) and adding the words ''the Agency'' in their place.

§ 1962.46 [Amended]

73. Section 1962.46 is amended by:

a. removing the words ''an insured'' in the fourth sentence of the introductory text of paragraph (c) and adding the words ''a direct'' in its place;

b. removing all references to ''FmHA or its successor agency under Public Law 103–354'' and adding the words ''the Agency'' in their place, and

c. by removing all references to ''FmHA or its successor agency under Public Law 103–354's'' in paragraphs (b) through (d) and adding the words ''the Agency's'' in their place.

§ 1962.47 [Amended]

74. Section 1962.47 is amended:

a. by removing the words ''an insured'' in the first sentence of paragraph (b)(2)(iv) and adding the words ''a direct'' in its place;

b. by removing references to ''FmHA or its successor agency under Public Law 103–354'' in paragraphs (a)(3)(i), (b), introductory text, (b)(2)(i), (b)(2)(iv), and (c) introductory text, and adding the words ''the Agency'' in its place; and

c. by removing the phrase ''or its successor agency under Public Law 103–354 1965–14'' in the first sentence of paragraph (b)(2)(i).

Exhibit F of Subpart A—[Removed and Reserved]

75. Exhibit F of Subpart A is removed and reserved.

PART 1965—REAL PROPERTY

76. The authority citation for part 1965 is revised to read as follows:

Authority: 5 U.S.C. 301; 7 U.S.C. 1989; 42 U.S.C. 1480.

Subpart A—Servicing of Real Estate Security for Farm Credit Program Loans and Certain Note—Only Cases

§ 1965.13 [Amended]

77. Section 1965.13 is amended by:

a. removing the phrase ''FmHA or its successor agency under Public Law 103–354'' in paragraph (f)(4)(ii) and adding the words ''FSA Farm Credit Programs'' in its place; and

b. removing the references to ''§ 1924.57(c)(5)'' and § 1924.57(b)'' in paragraphs (f)(4)(ii)(A) and (B) and adding ''§ 1924.56'' in their place.

PART 1980—GENERAL

78. The authority citation for part 1980 is revised to read as follows:

Authority: 5 U.S.C. 301; 7 U.S.C. 1989; 42 U.S.C. 1480.

Subpart B—Farm Credit Programs Loans

§ 1980.101 [Amended]

79. Section 1980.101 is amended by:

a. removing the words ''Farmers Home Administration or its successor agency under Public Law 103–354'' in the first sentence of paragraph (a);

b. removing all references to ''FmHA or its successor agency under Public Law 103–354'' in paragraphs (a) and (b) and adding the word ''Agency'' in their place;

c. adding and reserving paragraphs (c)(1) and (c)(2);

d. removing the words ''Farmer Programs'' in paragraphs (a) and (b) and adding the words ''Farm Credit Programs'' in its place;

e. removing the phrase ''or its successor agency under Public Law 103–354'' in paragraph (e)(1), and

f. by revising paragraph (e)(2) to read as follows:

§ 1980.101 Introduction.

* * * * *

(e) * * *

(2) *Contract of Guarantee (Operating Loans—Line of Credit only).* Lenders desiring a guarantee on a ''line of credit'' will use the method contained in subpart A of this part. Line of credit loans are guaranteed in accordance with Form FmHA 1980–27, ''Contract of Guarantee (Line of Credit).'' Line of credit notes and agreements may not be sold by the originating lender, but the originating lender may use participating lenders in accordance with § 1980.119. Any amount advanced by the lender in excess of the line of credit ceiling set forth in the contract is not guaranteed by the Agency.

§ 1908.106 [Amended]

80. Section 1980.106(b) is amended by:

a. removing the words ''Farmer Programs'' in the definition of ''Applicant'' and adding the words ''Farm Credit Programs'' in its place;

b. removing the phrase ''FmHA or its successor agency under Public Law 103–354'' in the definition of *Approval official* and adding the word *Agency* in its place; and

c. adding the definition of *Agency* before the definition of *Applicant.*

* * * * *

Agency. Farm Service Agency, its county and State committees and their personnel, and any successor agency.

* * * * *

§ 1980.108 [Amended]

81. Section 1980.108 is amended by:

a. removing the phrases ''FmHA or its successor agency under Public Law 103–354'' and ''FmHA or its successor agency under Public Law 103–354's'' in paragraph (a)(1)(iii) and adding the words ''the Agency'' and ''the Agency's'' in their place respectively, and

b. by revising paragraphs (a)(1)(i) and (a)(2)(i) to read as follows:

§ 1980.108 General provisions.

(a) * * *

(1) * * * (i) The lender is responsible for seeing that security is obtained and maintained to protect the interests of the lender and the Agency.

* * * * *

(2) * * * (i) Guarantees of parent, subsidiary, or affiliated companies may be required. Guarantees will be required in an amount which reasonably assures repayment of the loan or line of credit and provides sufficient security. If a review of all credit factors indicates the need for additional security, the lender or the Agency may require additional personal and corporate guarantees. The lender or the Agency also may require that such guarantees be secured.

* * * * *

82. Section 1980.109 is amended by revising the introductory text of paragraph (b) to read as follows:

§ 1980.109 Promissory notes, line of credit agreements, security instruments, and financing statements.

* * * * *

(b) *Financing statements.* Commercial financing statement forms that comply with state laws and regulations may be used. If the financing statement does not already contain the following provisions, they must be inserted to meet Agency requirements:

* * * * *

§ 1980.103 [Amended]

83. Section 1980.110 is amended by:

a. removing the phrase ''FmHA or its successor agency under Public Law 103–354'' in the introductory text, in the first and last sentences of paragraph (a), the second time it appears in paragraph (b) and in paragraph (c) and adding the words ''the Agency'' and ''The Agency'' in their place;

b. removing the phrase ''FmHA or its successor agency under Public Law 103–354 Instruction 440.1'' in the last sentence of paragraph (a) and adding the words ''FmHA Instruction 440.1'' in its place; and

c. by removing the phrase ''Form FmHA or its successor agency under Public Law 103–354 1980–24'' in paragraph (b) and adding the words ''Form FmHA 1980–24'' in its place.

84. Section 1980.113 is amended by:

a. removing the phrase ''FmHA or its successor agency under Public Law 103–354'' wherever it appears in the introductory text and adding the word ''Agency'' in its place;

b. removing the phrase ''or its successor agency under Public Law 103–354'' in paragraphs (a), introductory text, (a)(1), (a)(2), (a)(5), and (b), introductory text;

c. removing the words ''cash flow'' in the third sentence in the introductory text of paragraph (a)(7) and adding the words ''case file'' in its place;

d. removing the phrase ''FmHA or its successor agency under Public Law 103–354'' in paragraph (a)(7)(ii) and adding the word ''Agency'' in its place;

e. removing the words ''a disaster(s)'' in the introductory text of paragraph (a)(7)(ii)(D) and adding the word ''disasters'' in its place;

f. revising paragraphs (a)(6), (a)(7)(i)(B), (a)(7)(ii)(B) and (C), (a)(7)(ii)(D)(*1*), and (a)(11)(ii) and (iii); and

g. adding new paragraphs (a)(12) and (c) to read as follows:

§ 1980.113 Receiving and processing applications.

* * * * *

(a) * * *

(6) *Proposed loan agreement or line of credit agreements between the applicant and lender.* Loan agreements or line of credit agreements will address at least the following:

(i) Improved management or production practices to be implemented.

(ii) Requirements for accounting, recordkeeping, and financial reporting.

(iii) Limitations on the purchase or sale of capital assets.

(iv) Prohibitions against incurring additional debt or cosigning for the liabilities of others.

(v) Limits on family living expenses.

(vi) Insurance requirements and collateral inspections.

(vii) Purposes for which loan or line of credit funds can be used.

(viii) Interest rates and terms; how and when the rate may fluctuate; term of loan; and conditions related to the repayment, renewal, etc., of loans with balloon payments.

(ix) Credit ceiling, special limitations, and conditions precedent to annual readvancement or continuation of loans or lines of credit.

(x) Limitations on salaries paid to entity members, hired labor, or consultants. Limitations on withdrawals in the case of joint operations and partnerships.

(7) * * *

(i) * * *

(B) Government loan rates, *i.e.,* FSA (formerly ASCS) target prices.

* * * * *

(ii) * * *

(B) For those farmers with less than a 5-year production or yield history, the applicant's available production history will be utilized.

(C) For those farmers whose actual history is insufficient to provide an accurate estimate, consider the use of FSA Farm Programs actual records for specific farms, county averages, State averages, university data, or any other reliable sources of information that are acceptable to the lender, applicant, and the Agency.

(D) * * *

(*1*) County average yields will be used for disaster years in developing an historical base yield. If the applicant's disaster years are less than the county average yields, county average yields will be used for those years. If county average yields are not available, State average yields will be used. Once the yield base has been established, plus or minus adjustments may be made to reflect production trends or changes that will impact expected yields during the projected farm budget period. Adjustments can be made providing there is factual evidence to demonstrate that the yield used in the farm plan is the most reliable.

* * * * *

(11) * * *

(ii) A current, personal balance sheet from all members of a cooperative, joint operators of a joint operation, partners of a partnership, or stockholders of a corporation. To be current, the balance sheet must be no more than 90 days old on the date that the application is completed.

(iii) A current balance sheet of the cooperative, corporation, partnership, or joint operation.

* * * * *

(12) A concise narrative summary of the following items:

(i) The agricultural and nonagricultural enterprises comprising the operation, including any proposed to be added or dropped.

(ii) The real estate used in the operation including significant planned and existing improvements, significant conservation practices in effect, adequacy of facilities, external factors of negative or positive impact.

(iii) Chattel property, including the adequacy of machinery, equipment, and foundation livestock to carry out the existing or proposed operation.

(iv) The farm business organization and key personnel. For example, the legal business structure, roles, functions and backgrounds of key individuals, the accounting and record keeping system, and agreements for transferring or dissolving the business.

(v) Goals. The short-term and long-term business goals of the operation.

(vi) Historical financial data.

(vii) Planned changes. Changes to overcome negative trends or other aspects of the operation. Consider such items as improved production techniques or management practices.

* * * * *

(c) *Market Placement applications.* This paragraph explains the requirements for market placement applications for lenders that have expressed interest in financing or refinancing specific direct loan applicants described under § 1910.4 (c), as well as for ''commercial'' or ''standard'' borrowers defined under § 1951.252. If more than one lender is interested in providing financing, the direct loan applicant or borrower will rank the lenders in order of preference, and the Agency will present the market placement applications in that order. A market placement application should be ready for immediate acceptance by the lender and approval by the Agency, subject to the terms and conditions of the Request for Obligation of Funds and Conditional Commitment. The items needed for a market placement application are to be packaged by the Agency and consist of the following:

(1) Form FmHA 1980–25 will be prepared using estimated interest rates and terms. All other items required, with the exception of the loan or line of credit agreement, for a complete application under this section will be attached. The lender will submit the loan or line of credit agreement prior to the Agency's issuance of the Conditional Commitment.

(2) Form FmHA 1940–3, ''Request for Obligation of Funds—Guaranteed Loans.''

85. Section 1980.114 is amended by:

a. removing the introductory text; by removing and reserving paragraphs (a) and (b);

b. by redesignating paragraphs (c) and (d) as paragraphs (d) and (e), respectively;

c. by removing and reserving the ADMINISTRATIVE section;

d. by revising the section heading;

e. by removing and reserving the redesignated paragraph (d); by revising redesignated paragraph (e); and by adding a new paragraph (c) to read as follows:

§ 1980.114 Evaluation and assessment of applications.

* * * * *

(c) *Agency analysis of complete application.* In addition to other applicable requirements under this part, an application for a guarantee must meet the following conditions:

(1) The proposed loan or line of credit is for authorized purposes, and the amounts of borrowed capital are appropriate to successfully carry on the agricultural operation.

(2) The operation's capital position is adequate taking its strengths and weaknesses into consideration.

(3) The applicant has adequate repayment ability and has a reasonable chance of securing non-guaranteed commercial credit for the operation in the future. Developing an acceptable farm plan is the responsibility of the lender and its borrower.

(4) Security is adequate, values are reasonable, and loan terms are consistent with the useful life of the security and Agency regulations.

(5) The projected budget is reasonable in light of the applicant's stated goals.

* * * * *

(e) *Indication of acceptability.* If the Agency's evaluation indicates that the guarantee may be approved, the Agency will consider the guarantee request for eligibility.

§ 1980.115 [Amended]

86. Section 1980.115 is amended by:

a. revising the heading to read ''*Eligibility review.*'';

b. removing paragraphs (a) through (d) and the ADMINISTRATIVE section;

c. removing all references in the introductory text to ''County Committee'' and adding the word ''Agency,'' in their place; and

d. by removing the reference to ''FmHA or its successor agency under Public Law 103–354'' in the introductory text.

§ 1980.125 [Amended]

87. Section 1980.125 is amended by:

a. removing the phrase ''FmHA or its successor agency under Public Law 103–354'' in paragraphs (a), introductory text, (b)(3), (c) introductory text, (d)(5), and in the seventh and eighth lines of paragraph (d)(4) and adding the words ''the Agency'' in its place; and

b. by removing the phrase ''or its successor agency under Public Law 103–354'' from paragraphs (b)(1)(i), (c)(4), (d)(3), (d)(6) and in the second and third lines of paragraph (d)(4).

§ 1980.126 [Amended]

88. Section 1980.126 is amended by removing the phrase ''FmHA or its successor agency under Public Law 103–354'' in the last sentence and

adding the words ''the Agency'' in its place.

§ 1980.129 [Amended]

89. Section 1980.129 is amended by:

a. removing the ADMINISTRATIVE section;

b. removing the phrase ''FmHA or its successor agency under Public Law 103–354'' in paragraph (a) and adding the words ''the Agency'' in its place; and

c. revising the introductory text to read as follows:

§ 1980.129 Planning and performing development.

The lender is responsible for seeing that any buildings or other improvements or major land development to be paid for with loan funds are properly completed within a reasonable period of time. The lender is responsible for perfecting the required lien in the security, which includes ensuring that the security property is free of any mechanic's, materialmen's, or other liens which would affect lien priority. All major construction, major repairs, and major land development must be performed by qualified parties under conditions considered standard and prudent by commercial lenders and their financial regulators. Form FmHA 449–11, ''Certificate of Acquisition or Construction,'' must be completed and submitted to the Agency. In connection with construction, the lender is responsible for:

* * * * *

§ 1980.130 [Amended]

90. Section 1980.130 is amended by removing the ADMINISTRATIVE section.

§ 1980.136 [Amended]

91. Section 1980.136 is amended by:

a. removing the phrase ''FmHA or its successor agency under Public Law 103–354'' in paragraphs (a) and (b) and adding the words ''The Agency's'' and ''Agency'' respectively in their place; and

b. by removing the word ''instrument(s)'' in paragraph (d) and adding the word ''instruments'' in its place.

§§ 1980.148, 1980.149 and 1980.153 [Removed and Reserved]

92. In Part 1980 §§ 1980.148, 1980.149, and 1980.153 are removed and reserved.

§ 1980.175 [Amended]

93. Section 1980.175(b) is amended by:

a. removing the phrase ''FmHA or its successor agency under Public Law 103–354'' in the introductory text and adding the word ''Agency'' in its place the first time it appears and to read ''FmHA'' the second time it appears and to read ''Agency'' in paragraph (b)(1)(i);

b. removing the reference to ''§ 1980.106(b)(21)'' in the first sentence of paragraph (b)(1)(i) and adding the reference to ''§ 1980.106(b)'' in its place.

Exhibit A of Subpart B—[Amended]

94. Exhibit A of subpart B is amended by:

a. removing the phrase ''FmHA or its successor agency under Public Law 103–354'' in paragraph III.A and adding the words ''the Agency'' in its place in the next to last sentence and to remove the phrase ''or its successor agency under Public Law 103–354'' everywhere else it appears in that paragraph;

b. removing the phrase ''or its successor agency under Public Law 103–354'' in paragraph III.C; and

c. by revising paragraph IV to read as follows:

IV. *Agency Actions.* The Agency will complete the evaluation described in § 1980.114 in any case where the approval official determines an independent analysis is needed before approval or denial of a request for guarantee. The Agency may request additional information, review the lender's ''complete application'' file or make an independent evaluation of the application, if needed, to determine whether the applicant is eligible, the loan or line of credit is for authorized purposes, there is reasonable assurance of repayment ability, and sufficient collateral and equity is available. The Agency will make the final determinations on the eligibility of applicants for a guaranteed OL loan or line of credit, an SW loan, or FO loan, and the purposes and terms of such loans or lines of credit.

A. [Reserved].

B. [Reserved].

Each approved lender who currently has an Approved Lender Agreement executed prior to January 6, 1988, will be required to execute a new Approved Lender Agreement. If liquidation of the account becomes imminent, the Lender will consider the borrower for Interest Assistance and request a determination of the borrower's eligibility by the Agency. The lender may not initiate foreclosure action on the loan until 60 days after a determination has been made on the borrower's eligibility to participate in the Interest Assistance Program.

* * * * *

Signed at Washington, DC, on July 2, 1996.

Eugene Moos,

Under Secretary for Farm and Foreign Agricultural Services.

Jill Long Thompson,

Under Secretary for Rural Development.

[FR Doc. 96–17266 Filed 7–8–96; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Part 214

[INS No. 1765–96]

RIN 1115–AE40

Adding Oakland, California, and Sanford, Florida, to the List of Ports of Entry Accepting Applications for Direct Transit Without Visa

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Final rule.

SUMMARY: This rule amends the Immigration and Naturalization Service (the Service) regulations by adding Oakland, California, and Sanford, Florida, to the list of ports of entry where, except for transit from one part of foreign contiguous territory to another part of the same territory, an alien must make application for admission to the United States for direct transit without visa. This change is necessary to accommodate the increase in international commerce service Oakland, California, and Sanford, Florida.

EFFECTIVE DATE: July 9, 1996.

FOR FURTHER INFORMATION CONTACT: Robert F. Hutnick, Assistant Chief Inspector, Immigration and Naturalization Service, 425 I Street, NW., Room 7228, Washington, DC 20536, telephone number (202) 616–7499.

SUPPLEMENTARY INFORMATION: This final rule adds Oakland, California, and Sanford, Florida, to 8 CFR 214.2(c)(1) as ports of entry where, except for transit from one part of foreign contiguous territory to another part of the same territory, application for direct transit without visa must be made. The Orlando Sanford Airport in Sanford, Florida, will be adding additional international passenger service, specifically arrivals transiting between the United Kingdom and Mexico. By allowing this airport to accept applications for direct transit without visa, the Orlando Sanford Airport will be able to accommodate these transit air

passengers. The Oakland International Airport has added international passenger service between France and Tahiti. By allowing this airport to accept applications for direct transit without visa, Oakland International Airport will be able to accommodate these transit air passengers.

Compliance with 5 U.S.C. 553 as to notice of proposed rulemaking and delayed effective date is unnecessary as this rule relates to agency management. Since this rule pertains to agency ''practice and procedures'' it does not require Congressional review necessitated by 5 U.S.C. § 801.

Regulatory Flexibility Act

The Commissioner of the Immigration and Naturalization Service, in accordance with Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and, by approving it, certifies that this rule will not have a significant economic impact on a substantial number of small entities. This rule merely allows the Oakland, California, and the Sanford, Florida, airports to accommodate international passengers by providing authority to accept applications for direct transit without visa. This rule will facilitate travel for the public.

Executive Order 12866

This rule is not considered by the Department of Justice, Immigration and Naturalization Service, to be a ''significant regulatory action'' under Executive Order 12866, section 3(f), Regulatory Planning and Review, and the Office of Management and Budget has waived its review process under section 6(a)(3)(A).

Executive Order 12612

The regulation proposed herein will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 8 CFR Part 214

Administrative practice and procedure, Aliens, Passports and visas.

Accordingly, part 214 of chapter I of title 8 of the Code of Federal Regulations is amended as follows:

PART 214—NONIMMIGRANT CLASSES

1. The authority citation for part 214 continues to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1182, 1184, 1186a, 1187,1221, 1281, 1282; 8 CFR part 2.

§ 214.2 [Amended]

2. In § 214.2, paragraph (c)(1) is amended, in the fourth sentence, by adding ''Oakland, CA,'' immediately after ''Norfolk, VA,'' and ''Sanford, FL,'' immediately after ''San Diego, CA,'' to the listing of ports of entry authorized to accept direct transit without visa applications.

Dated: June 25, 1996.

Doris Meissner,

Commissioner, Immigration and Naturalization Service.

[FR Doc. 96–17264 Filed 7–8–96; 8:45 am]

BILLING CODE 4410–10–M

NUCLEAR REGULATORY COMMISSION

10 CFR Part 53

RIN 3150–AF47

Removal of 10 CFR Part 53—Criteria and Procedures for Determining the Adequacy of Available Spent Nuclear Fuel Storage Capacity

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to remove provisions concerning the ''Criteria and Procedures for Determining the Adequacy of Available Spent Nuclear Fuel Storage Capacity'' from the Code of Federal Regulations. This Part of the Commission's regulations is no longer applicable because the statutory timeframe for its implementation has expired.

DATE: This final rule is effective on August 8, 1996.

FOR FURTHER INFORMATION CONTACT: Gordon Gundersen, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6195.

SUPPLEMENTARY INFORMATION:

Background

10 CFR Part 53 established procedures for nuclear power plant owners to follow for obtaining a determination from the NRC that the plant can not provide adequate spent nuclear fuel storage capacity. The regulations in this part established procedures and criteria for making the determination required by section 135(b) of the Nuclear Waste Policy Act of 1982 (96 Stat. 2201 and 2233) that an owner or operator of a civilian nuclear power reactor could not reasonably provide adequate spent nuclear fuel storage capacity at the reactor site, or at any other reactor it operates, when needed to ensure the continued orderly operation of the reactor. These regulations also required that the owner or operator diligently pursue licensed alternatives to the use of Federal storage capacity for the storage of spent nuclear fuel expected to be generated in the future.

Civilian nuclear power reactor operators who wanted the Commission to make a determination under 10 CFR Part 53 had to file a request by June 30, 1989. The Commission was to process the request and make a determination before January 1, 1990. Section 53.11(b) placed a time limitation of June 30, 1989 (with an outside date of January 1, 1990 for special circumstances), on the filing of requests for a Commission determination on the adequacy of available spent fuel storage capacity. This was based on the January 1, 1990, limitation in Section 136(a) of the Nuclear Waste Policy Act on the ability of Department of Energy to enter into contracts for the interim storage of spent fuel based on a Commission determination. These dates have long passed and this Part of the Commission's regulations is no longer applicable because the statutory timeframe for its implementation has expired.

The storage of spent nuclear fuel at NRC licensed nuclear power plants is not affected by removing 10 CFR Part 53 because 10 CFR Part 50 provides the regulatory basis for licensing both wet and dry modes of spent fuel storage at nuclear power reactors. 10 CFR Part 72 provides the regulatory basis for licensing spent nuclear fuel storage in Independent Spent Fuel Storage Installations or Monitored Retrievable Storage Installations. These regulations are not affected by the removal of 10 CFR Part 53.

In accordance with 10 CFR 2.804(d)(2) of the Commission's regulations, the Commission is issuing a final rule withdrawing 10 CFR Part 53, rather than using the normal notice and comment process for agency rulemakings. In this case, the Commission finds that there is good cause to dispense with notice and public comment as unnecessary. As noted above, the statutory time period within which Federal interim storage under this rule could be implemented has long passed, and the Commission has no discretion to entertain any requests for Federal interim storage under this rule. Furthermore, little interest has been shown in the interim

storage procedures in 10 CFR Part 53, and the Commission received no requests for interim storage since its promulgation in 1985. Under these circumstances, the Commission believes that public comment is unnecessary. The action will become effective on August 8, 1996.

Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(2). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

Paperwork Reduction Act Statement

This final rule contains no information collection requirements and, therefore, is not subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Existing requirements, which are being discontinued, were approved by the Office of Management and Budget, approval number 3150–0126.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Regulatory Analysis

A regulatory analysis has not been prepared for this final rule because this final rule is considered a minor, non-substantive amendment and has no economic impact on NRC licensees or the public.

Small Business Regulatory Enforcement Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109 does not apply to this final rule because these amendments do not involve any provisions which would impose backfits as defined in 10 CFR 50.109(a)(1). Therefore, a backfit analysis is not required for this final rule.

List of Subjects in 10 CFR Part 53

Administrative practice and procedure, High-level waste, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements, Spent fuel, Waste treatment and disposal.

PART 53—[REMOVED]

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954 (42 U.S.C. 2201), as amended; the Energy Reorganization Act of 1974 (42 U.S.C. 5841), as amended; and 5 U.S.C. 552 and 553; the NRC is removing 10 CFR Part 53.

Dated at Rockville, Maryland, this 25th day of June 1996.

For the Nuclear Regulatory Commission.

James M. Taylor,

Executive Director for Operations.

[FR Doc. 96–17447 Filed 7–8–96; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 95–CE–101–AD; Amendment 39–9690; AD 96–09–08 R1]

RIN 2120–AA64

Airworthiness Directives; Aviat Aircraft Inc. Models S–2A, S–2B, and S–2S Airplanes (formerly Pitts Models S–2A, S–2B, and S–2S airplanes)

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment revises Airworthiness Directive (AD) 96–09–08, which currently requires inspecting the longerons aft of the rear cabane struts for cracks, and if cracked, prior to further flight, repairing the cracks. The current AD is applicable to Aviat Aircraft Inc. (Aviat), Models S–2A, S–2B, and S–2S airplanes (formerly Pitts Models S–2A, S–2B, and S–2S airplanes). This action requires the same action as AD 96–09–08; however, after AD 96–09–08 was issued, the FAA was notified by the manufacturer that the compliance time in the service bulletin was changed, and as a result, the issue date for the service bulletin was changed. This revision will ensure that the owner and operators are using the most up-to-date service bulletin applicable to the required actions in this AD. The actions specified by this AD are intended to prevent cracking and subsequent failure of the longerons resulting in possible loss of control of the airplane.

DATES: Effective July 26, 1996.

The original Aviat Service Bulletin No. 24, dated February 8, 1996 was incorporated by reference and approved by the Director of the Federal Register to become effective May 20, 1996 (61 FR 19540, May 2, 1996). The incorporation by reference of Aviat Service Bulletin No. 24, dated March 20, 1996 that is applicable to this revised AD and listed in the regulations is approved by the Director of the Federal Register as of July 26, 1996.

Comments for inclusion in the Rules Docket must be received on or before August 30, 1996.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket 95–CE–101–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Service information that applies to this AD may be obtained from Aviat Aircraft Inc., The Airport-Box No. 1240, 672 South Washington Street, Afton, Wyoming, 83110; telephone (307) 886–3151; facsimile (307) 886–9674. This information may also be examined at the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket 95–CE–101–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Roger Caldwell, Project Engineer, FAA, Denver Aircraft Certification Office, 5440 Roslyn St., suite 133, Denver, Colorado 80216; telephone (303) 286–5683; facsimile (303) 286–5689.

SUPPLEMENTARY INFORMATION: Airworthiness Directive 96–09–08, Amendment 39–9584, (61 FR 19540, May 2, 1996) is applicable to Aviat Aircraft Inc., Models S–2A, S–2B, and S–2S airplanes (formerly Pitts Models S–2A, S–2B, and S–2S airplanes) and currently requires inspecting the longerons around the rear cabane struts for cracks, and if no cracks are found, continue repetitively inspecting the airplane. If cracks are found during any inspection, prior to further flight, repair any cracks found according to the approved repair scheme provided by the Denver ACO manager.

Accomplishment of the actions of AD 96–09–08 is required in accordance with Aviat Aircraft Inc. Service Bulletin (SB) No. 24, dated February 8, 1996, which has been revised and replaced by Aviat SB No. 24, dated March 20, 1996.

Explanation of the Need for the Revision

The service bulletin incorporated into AD 96–09–08 contains identical requirements as this revised AD, except for the change in the date to March 20, 1996 and the change to the compliance time.

The FAA determined that the revised service bulletin should be incorporated because the previous service bulletin dated February 8, 1996 was not made available to the owners and operators by the manufacturer until after the service bulletin was changed. The FAA cannot determine if some of the owners/operators of the affected airplanes may have already complied with AD 96–09–08 in accordance with Aviat SB No. 24, dated February 8, 1996.

Since the service bulletin must be available in order for the owners/operators to comply with this action, this AD revises AD 96–09–08 by (1) retaining the initial inspection, the repetitive inspection, and repair required by AD 96–09–08; and (2) incorporating the revised service bulletin to require accomplishment of the actions in accordance with Aviat SB No. 24, dated March 20, 1996.

Since it was found that immediate corrective action was required, notice and opportunity for prior public comment thereon were impracticable and contrary to the public interest, and good cause existed to make AD 96–09–08 effective in less than 30 days to all known U.S. operators of Aviat Models S–2A, S–2B, and S–2S airplanes. These conditions still exist, and the AD revision is hereby published in the Federal Register as an amendment to section 39.13 of the Federal Aviation Regulations (14 CFR 39.13) to make it effective to all persons. The actions are to be done in accordance with the instructions in Aviat SB No. 24, dated March 20, 1996.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting immediate flight safety and, thus, was not preceded by notice and opportunity to comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenters ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 95–CE–101–AD.'' The postcard will be date stamped and returned to the commenter.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation and that must be issued immediately to correct an unsafe condition in aircraft, and is not a ''significant regulatory action'' under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket (otherwise, an evaluation is not required). A copy of it, if filed, may be obtained from the Rules Docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 USC 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13, Amendment 39–9584, (61 FR 19540, May 2, 1996), is revised to read as follows:

96–09–08 R1. Aviat Aircraft Inc.: Amendment 39–9690; Docket No. 95–CE–101–AD R1. Revises AD 96–09–08, Amendment 39– 9584.

Applicability: Models S–2A, S–2B, and S–2S Airplanes (formerly Pitts Models S–2A, S–2B, and S–2S airplanes), all serial numbers, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (d) of this AD to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any airplane from the applicability of this AD.

Compliance: Required at the accumulation of 300 hours total time-in-service (TIS), or within the next 25 hours TIS, whichever occurs later, and thereafter at intervals not to exceed 25 hours TIS, unless already accomplished in accordance with AD 96–09–08, effective date May 20, 1996 and corresponding Aviat Service Bulletin (SB) No. 24, dated February 8, 1996.

Note 2: The compliance time of this revised AD takes precedence over the compliance time stated in Aviat SB No. 24, dated March 20, 1996.

To prevent cracking and subsequent failure of the longerons resulting in possible loss of control of the airplane, accomplish the following:

(a) Inspect (using a 10x magnifying glass) the longerons aft of the rear cabane struts for cracks in accordance with paragraphs 1.) through 5.) in the Aviat Service Bulletin (SB) No. 24, dated March 20, 1996. If cracks are found during any inspection required by this AD, prior to further flight, contact the Manager of the Denver Aircraft Certification Office (ACO) for an approved repair scheme.

(b) Prior to further flight, repair any cracks found in accordance with the approved

repair scheme provided by the Denver ACO Manager.

(c) Report the results of the initial inspection to the Manager of the Denver Aircraft Certification Office (ACO), FAA, Denver Aircraft Certification Office, 5440 Roslyn St., suite 133, Denver, Colorado, 80216, within 10 days of the inspection. The information provided should include airplane model number, serial number, registration number, location of cracks found, number of cracks, and total TIS. Reporting requirements have been approved by the Office of Management and Budget and assigned OMB control number 2120–0056.

(d) An alternative method of compliance or adjustment of the initial or repetitive compliance times that provides an equivalent level of safety, may be approved by the Manager, Roger Caldwell, Project Engineer, FAA, Denver Aircraft Certification Office, 5440 Roslyn St., suite 133, Denver, Colorado, 80216. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Denver Aircraft Certification Office.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Denver Aircraft Certification Office.

(e) The inspections and repairs required by this AD shall be done in accordance with Aviat Aircraft Inc. Service Bulletin No. 24, dated March 20, 1996, or in accordance with Aviat Aircraft Inc. Service Bulletin No. 24, dated February 8, 1996, previously incorporated by reference in the Federal Register (61 FR 19540, May 2, 1996) and applicable to AD 96–09–08. This 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 obtained from Aviat Aircraft Inc., The Airport-Box No. 1240, 672 South Washington Street, Afton, Wyoming, 83110. Copies may be inspected at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(f) This amendment (39–9690) revises AD 96–09–08, Amendment 39–9584.

(g) This amendment (39–9690) becomes effective on July 26, 1996.

Issued in Kansas City, Missouri, on June 25, 1996.

James E. Jackson,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–17294 Filed 7–8–96; 8:45 am]

BILLING CODE 4910–13–P

14 CFR Part 39

[Docket No. 95–NM–124–AD; Amendment 39–9687; AD 96–14–05]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 767 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to certain Boeing Model 767 series airplanes, that currently requires an inspection of the control rods of the outboard leading edge slat, and follow-on actions (including repetitive ultrasonic inspections), if necessary. For certain airplanes, that AD also requires replacement of the control rod ends and attach bolts. It also provides for an optional terminating action for follow-on repetitive inspections. That AD was prompted by reports of cracks and worn attach bolts of the control rods of the leading edge outboards slats of the wings due to the high breakout torque in the joint of the control rod end. This amendment requires the installation of the previously optional terminating action. The actions specified by this AD are intended to prevent reduced controllability of the airplane and damage in the slat structure or fixed leading edge of the wing, as a result of cracks and worn attach bolts.

DATES: Effective August 13, 1996.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of August 13, 1996.

ADDRESSES: The service information referenced in this AD may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Kristin Larson, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington; telephone (206) 227–1760; fax (206) 227–1181.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding AD 90–20–16, amendment 39–6726 (55 FR 37858, September 14, 1990), which is applicable to certain Boeing Model 767 series airplanes, was published in the Federal Register on December 13, 1995 (60 FR 63990). The action proposed to continue to require a one-time visual inspection to determine the date of manufacture of the control rods of the outboard leading edge slat, and follow-on actions (i.e., repetitive ultrasonic inspection), if necessary. The action also proposed to continue to require replacement of the control rod ends and attach bolts, for certain airplanes. For operators accomplishing the (follow-on) repetitive ultrasonic inspections, that action proposed to require replacement of the control rod with a new control rod manufactured after June 1983; this replacement would constitute terminating action for the repetitive inspections.

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

Request To Add a Visual Inspection

One commenter requests that the FAA revise paragraph (a)(2)(i) of the proposal to require a visual inspection to detect cracks of the control rods, prior to further flight, rather than the proposed ultrasonic inspection. The commenter suggests that the proposed ultrasonic inspection be accomplished within 300 flight hours following accomplishment of the visual inspection. The commenter points out that the control rods currently are being inspected ultrasonically at 2,000 flight cycles/15-month intervals in accordance with AD 90–20–16. Since the ultrasonic inspections will identify cracks prior to rod failure, the commenter states that it is unnecessary to accomplish an additional ultrasonic inspection.

The FAA finds that clarification is necessary. Paragraph (a)(2)(i) of this AD merely restates the existing requirements of paragraph A.2. of AD 90–20–16. Therefore, for operators who have previously accomplished at least the initial ultrasonic inspection in accordance with AD 90–20–16, paragraph (a)(2)(i) of this AD requires that the next scheduled inspection be performed within 2,000 landings or 15 months, whichever occurs first, after the last inspection performed in accordance with paragraph A.2. of AD 90–20–16. In light of this, the FAA finds that the addition of a visual inspection, as suggested by the commenter, is unnecessary. NOTE 2 has been added to this final rule to clarify the restatement

of the existing requirements of AD 90–20–16.

Request To Include Reference to Additional Service Bulletins

Two commenters request that the FAA revise paragraph (a)(2)(ii) of the proposed rule to reference Revision 2 of Boeing Service Bulletin 767–57–0021, dated July 26, 1990, as an additional source of service information for accomplishment of the replacement. One of the commenters points out that this will eliminate unnecessary processing of an alternative method of compliance.

The FAA concurs partially. The FAA has determined that the procedures for replacement of the control rod, specified in Revision 2 of Boeing Service Bulletin 767–57–0021, are identical to those procedures in Revision 5 of the service bulletin (which is referenced in the AD as the appropriate source of service information). In addition, the FAA has determined that Revision 3, dated June 20, 1991, and Revision 4, dated March 19, 1992, of Boeing Service Bulletin 767–57–0021 also contain these identical replacement procedures. The FAA has revised the final rule by adding a new NOTE 2 to clarify that accomplishment of the replacement in accordance with Revision 2, Revision 3, or Revision 4 of Service Bulletin 767–57–0021, is considered acceptable for compliance with paragraph (a)(2)(ii) of the AD. In addition, since paragraph (b) of the final rule also contains these identical replacement procedures, the FAA has also added a similar Note 3 to that paragraph.

Request To Correct Referenced Service Bulletin Number

One commenter notes that the service bulletin number referenced in paragraph (b) of the proposal should be corrected to 767–57–0021. The FAA acknowledges that it inadvertently referenced the incorrect service bulletin number (i.e., 767–57–0221) in paragraph (b) of the proposal. Therefore, the FAA has revised paragraph (b) of the final rule to reference service bulletin number 767–57–0021.

Request for Assurance of Parts Availability

Two commenters support the rule, but question whether the manufacturer of the control rod assemblies can produce the quantity of required parts within the proposed compliance time.

The FAA has contacted to the manufacturer who has advised that ample parts are currently available; therefore, obtaining them within the required compliance time should not pose a problem for any affected operator. However, under the provisions of paragraph (c) of the final rule, the FAA may approve requests for adjustments to the compliance time if data are submitted to substantiate that such an adjustment would provide an acceptable level of safety.

Conclusion

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the changes previously described. The FAA has determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Cost Impact

There are approximately 271 Boeing Model 767 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 193 airplanes of U.S. registry will be affected by this proposed AD.

The actions that are currently required by AD 90–20–16 take approximately 21 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Required parts cost approximately $5,500 per airplane. Based on these figures, the cost impact on U.S. operators of the actions currently required is estimated to be $1,304,680, or $6,760 per airplane.

For certain affected airplanes, the new replacement (terminating) action that is required by this new AD will take approximately 1 work hour per airplane to accomplish, at an average labor rate of $60 per work hour. The cost of the required replacement parts is estimated to be $5,500 per airplane. Based on these figures, the cost impact on U.S. operators of the new requirements of this AD is estimated to be $5,560 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, or on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–6726 (55 FR 37858, September 14, 1990), and by adding a new airworthiness directive (AD), amendment 39–9687, to read as follows:

96–14–05 Boeing: Amendment 39–9687. Docket 95–NM–124–AD. Supersedes AD 90–20–16, Amendment 39–6726.

Applicability: Model 767 series airplanes; as listed in Boeing Service Bulletin 767–57–0021, Revision 1, dated September 14, 1989, or Revision 5, dated June 15, 1995; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not

been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

Note 2: Paragraphs (a), (a)(1), (a)(1), (a)(2), and (a)(2)(i) of this AD merely restate the initial and repetitive inspections contained in paragraphs A.1. and A.2. of AD 90–20–16, amendment 39–6726. Therefore, for operators who have previously accomplished at least the initial inspection in accordance with AD 90–20–16, paragraph (a)(2)(i) of this AD requires that the next scheduled inspection be performed within 2,000 landings or within 15 months, whichever occurs first, after the last inspection performed in accordance with paragraph A.2. of AD 90–20–16.

To prevent loss of the pilot's ability to control the affected slat, which could adversely affect the controllability of the airplane, accomplish the following:

(a) For airplanes having line positions 1 through 235 inclusive: Within the next 1,200 landings or 9 months after October 23, 1990 (the effective date of AD 90–20–16, amendment 39–6726), whichever occurs first, unless accomplished within the last 800 landings or 6 months, whichever occurs later, perform a visual inspection to determine the date of manufacture of the control rods of the outboard leading edge slat of the wings, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 767–57–0021, dated August 25, 1988; Revision 1, dated September 14, 1989; Revision 2, dated July 26, 1990; or Revision 5, dated June 15, 1995.

(1) If the date of manufacture (stamped on the control rod) is June 1983 or later, no further action is required by this paragraph.

(2) If the date of manufacture is illegible or is prior to June 1983, accomplish paragraphs (a)(2)(i) and (a)(2)(ii) of this AD.

(i) Prior to further flight, perform an ultrasonic inspection to detect cracks of the control rods in accordance with Figure 1 of Boeing Service Bulletin 767–57–0021, dated August 25, 1988, Revision 1, dated September 14, 1989, or Revision 2, dated July 26, 1990. If any crack or fracture is detected, prior to further flight, replace it in accordance with Figure 2 of the service bulletin. Repeat the ultrasonic inspection of the control rods manufactured prior to June 1983 thereafter at intervals not to exceed 2,000 landings or 15 months, whichever occurs first, until the replacement required by paragraph (a)(2)(ii) of this AD is accomplished.

(ii) Within 3,000 flight hours or 15 months after the effective date of this AD, whichever occurs later, replace the control rod with a new rod manufactured June 1983 or later, in accordance with Boeing Service Bulletin 767–57–0021, Revision 5, dated June 15, 1995. Accomplishment of this replacement constitutes terminating action for the repetitive inspection requirement of paragraph (a)(2)(i) of this AD.

Note 3: Replacement accomplished prior to the effective date of this amendment in accordance with Boeing Service Bulletin 767–57–0021, Revision 2, dated July 26, 1990; Revision 3, dated June 20, 1991, or Revision 4, dated March 19, 1992; is considered acceptable for compliance with paragraph (a)(2)(ii) of this AD.

(b) For airplanes having line number 1 through 264 inclusive, and 266 through 273 inclusive: Within the next 2,500 landings or 18 months after October 23, 1990 (the effective date of AD 90–20–16, amendment 39–6726, whichever occurs first, replace the control rod end and attach bolt with a new configuration control rod end and attach bolt on each wing, in accordance with Boeing Service Bulletin 767–57–0021, Revision 1, dated September 14, 1989; Revision 2, dated July 26, 1990; or Revision 5, dated June 15, 1995.

Note 4: Replacement accomplished prior to the effective date of this amendment in accordance with Boeing Service Bulletin 767–57–0021, Revision 3, dated June 20, 1991, or Revision 4, dated March 19, 1992, is considered acceptable for compliance with paragraph (b) of this AD.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 5: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(e) The inspections and replacements shall be done in accordance with Boeing Service Bulletin 767–57–0021, dated August 25, 1988; Boeing Service Bulletin 767–57–0021, Revision 1, dated September 14, 1989; Boeing Service Bulletin 767–57–0021, Revision 2, dated July 26, 1990; Boeing Service Bulletin 767–57–0021, Revision 3, dated June 20, 1991; Boeing Service Bulletin 767–57–0021, Revision 4, dated March 19, 1992; or Boeing Service Bulletin 767–57–0021, Revision 5, dated June 15, 1995. This 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 obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(f) This amendment becomes effective on August 13, 1996.

Issued in Renton, Washington, on June 27, 1996.

S.R. Miller,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–16950 Filed 7–8–96; 8:45 am]

BILLING CODE 4910–13–P

14 CFR Part 39

[Docket No. 96–NM–134–AD; Amendment 39–9688; AD 96–14–06]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 777–200 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to certain Boeing Model 777–200 series airplanes. This action requires repetitive inspections for broken lockwires on the bearing retainer nut of the pivot fittings of the horizontal stabilizer. This AD also requires eventual modification of the bearing nut retention means, which, when accomplished, terminates the repetitive inspections. This amendment is prompted by reports of broken lockwires on the bearing retainer nut of the pivot fittings of the horizontal stabilizer due to inadequate torquing of the nut. The actions specified in this AD are intended to prevent failure of the lockwires, which could result in loosening of the retainer nut for the pivot bearing of the horizontal stabilizer, and subsequent migration of the pivot bearing. This condition, if not corrected, could result in reduced controllability of the airplane.

DATES: Effective July 24, 1996.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 24, 1996.

Comments for inclusion in the Rules Docket must be received on or before September 9, 1996.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 96–NM–134–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

The service information referenced in this AD may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Stan Wood, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind

Avenue, SW., Renton, Washington; telephone (206) 227–2772; fax (206) 227–1181.

SUPPLEMENTARY INFORMATION: The FAA has received reports indicating that broken lockwires were found on the bearing retainer nut of the pivot fittings (bearings) of the horizontal stabilizer on Boeing Model 777–200 series airplanes. In one of these incidents, the retainer nut on the left and right sides of the horizontal stabilizer also was loose. The lockwires may have broken and the retainer nuts may have become loose due to inadequate torquing of the nut. Failure of the lockwire could result in loosening of the retainer nut for the pivot bearing of the horizontal stabilizer. Loss of the retainer nut could result in migration of the pivot bearing. This condition, if not corrected, could result in reduced controllability of the airplane.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Alert Service Bulletin 777–55A0003, Revision 1, dated June 20, 1996, which describes procedures for repetitive visual inspections to detect broken lockwires on the bearing retainer nut of the pivot fittings of the horizontal stabilizer (left and right sides). The alert service bulletin also describes procedures for eventual modification of the bearing nut retention means, which, when accomplished, eliminates the need for the repetitive inspections. The modification involves removing all lockwire on the nut, tightening the nut, and installing a new nut retainer. Accomplishment of the modification will prevent rotation of the bearing retainer nut.

Explanation of the Requirements of the Rule

Since an unsafe condition has been identified that is likely to exist or develop on other Model 777–200 series airplanes of the same type design, this AD is being issued to prevent reduced controllability of the airplane due to failure of the lockwire on the bearing retainer nut of the pivot fittings of the horizontal stabilizer, loosening of the retainer nut for the pivot bearing, and subsequent migration of the pivot bearing. This AD requires repetitive visual inspections for broken lockwires on the bearing retainer nut of the pivot fittings of the horizontal stabilizer (left and right sides). This AD also requires eventual modification of the bearing nut retention means, which, when accomplished, terminates the repetitive inspections. The actions are required to be accomplished in accordance with the alert service bulletin described previously.

Determination of Rule's Effective Date

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 96–NM–134–AD.'' The postcard will be date stamped and returned to the commenter.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a ''significant regulatory action'' under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

96–14–06 Boeing: Amendment 39–9688. Docket 96–NM–134–AD.

Applicability: Model 777–200 series airplanes; line positions 1, 3, 5, 7, 8, 9, 11, 12, 13, 15, 16, 17, 19, 20, 21, 22, and 23; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent reduced controllability of the airplane due to failure of the lockwire on the bearing retainer nut of the pivot fittings of the horizontal stabilizer, loosening of the retainer nut for the pivot bearing, and subsequent migration of the pivot bearing, accomplish the following:

(a) Within 150 flight cycles after the effective date of this AD: Perform a visual inspection for broken lockwires on the bearing retainer nut of the pivot fittings of the horizontal stabilizer (left and right sides), in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 777–55A0003, Revision 1, dated June 20, 1996.

(1) If no broken lockwire is found: Repeat the inspection within 500 flight cycles following accomplishment of the initial inspection. Within 1,000 flight cycles after accomplishment of the initial inspection, modify the bearing nut retention means in accordance with Figure 3 of the alert service bulletin. Following accomplishment of the modification, no further action is required by paragraph (a) of this AD.

(2) If only one broken lockwire is found: Repeat the inspection thereafter at intervals not to exceed 150 flight cycles. Within 450 flight cycles after accomplishment of the initial inspection, modify the bearing nut retention means in accordance with Figure 3 of the alert service bulletin. Following accomplishment of the modification, no further action is required by paragraph (a) of this AD.

(3) If two broken lockwires are found: Repeat the inspection and ensure that the bearing retainer nut is tight thereafter at intervals not to exceed 10 flight cycles. Within 100 flight cycles after accomplishment of the initial inspection, modify the bearing nut retention means in accordance with Figure 3 of the alert service bulletin. Following accomplishment of the modification, no further action is required by paragraph (a) of this AD.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(d) The actions shall be done in accordance with Boeing Alert Service Bulletin 777–55A0003, Revision 1, dated June 20, 1996. This 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 obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on July 24, 1996.

Issued in Renton, Washington, on June 27, 1996.

S.R. Miller,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–16949 Filed 7–8–96; 8:45 am]

BILLING CODE 4910–13–U

14 CFR Part 39

[Docket No. 96–NM–132–AD; Amendment 39–9692; AD 96–14–08]

RIN 2120–AA64

Airworthiness Directives; Fokker Model F28 Mark 0100 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Fokker Model F28 Mark 0100 series airplanes. This action requires modification of the radio altimeter wiring circuitry associated with the Automatic Flight Control Augmentation System (AFCAS). This amendment is prompted by a report indicating that the AFCAS does not properly monitor the radio altimeter status during automatic landing operations. The actions specified in this AD are intended to prevent erroneous indications and failure of the AFCAS to properly align, flare, and retard the airplane during automatic landing operations if a single radio altimeter were to fail.

DATES: July 24, 1996.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 24, 1996.

Comments for inclusion in the Rules Docket must be received on or before September 9, 1996.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 96–NM–132–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

The service information referenced in this AD may be obtained from Fokker Aircraft USA, Inc., 1199 North Fairfax Street, Alexandria, Virginia 22314. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tim Dulin, Aerospace Engineer, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (206) 227–2141; fax (206) 227–1149.

SUPPLEMENTARY INFORMATION: The Rijksluchtvaartdienst (RLD), which is the airworthiness authority for the Netherlands, recently notified the FAA that an unsafe condition may exist on certain Fokker Model F28 Mark 0100 series airplanes. The RLD advises that it has received a report indicating that the Automatic Flight Control Augmentation System (AFCAS) on these airplanes does not properly monitor the radio altimeter status during automatic landing (''LAND 2'') operations. As a result, an airplane may perform a ''LAND 2'' operation with only one radio altimeter that is operative. If the remaining altimeter were to fail or to lose track during the ''LAND 2'' operation, the ALIGN, FLARE, and/or RETARD modes will not be performed, even though the annunciations for these modes would still be indicated on the Electronic Flight Instrument System (EFIS). In this case, the flight crew may accept the EFIS annunciation that these maneuvers (modes) are being executed when, in fact, those maneuvers are not taking place. This condition could result in the flight crew not being aware that the AFCAS has not properly aligned, flared, and retarded the airplane during automatic landing operations.

Explanation of Relevant Service Information

Fokker has issued Service Bulletin SBF100–34–015, Revision 2, dated November 27, 1990, which describes procedures for a modification of the radio altimeter wiring circuitry associated with the AFCAS data-control jumper. This wiring change will allow the radio altimeters to remove the data from AFCAS data bus whenever a failure is detected. As a result, ''LAND 2'' operation is no longer possible with only one radio altimeter operative. The RLD classified this service bulletin as mandatory and issued Netherlands airworthiness directive (BLA) 90–023, Issue 2, dated May 23, 1990, in order to assure the continued airworthiness of these airplanes in the Netherlands.

FAA's Conclusions

This airplane model is manufactured in the Netherlands and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.19) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the RLD has kept the FAA informed of the situation described above. The FAA has examined the findings of the RLD, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of the Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design, this AD is being issued to prevent erroneous indications and failure of the AFCAS to properly align, flare, and retard the airplane during automatic landing operations when a single radio altimeter fails. This AD requires modification of the radio altimeter wiring circuitry associated with the AFCAS data-control jumper. The actions are required to be accomplished in accordance with the service bulletin described previously.

Cost Impact

None of the Model F28 Mark 0100 series airplanes affected by this action are on the U.S. Register. All airplanes included in the applicability of this rule currently are operated by non-U.S. operators under foreign registry; therefore, they are not directly affected by this AD action. However, the FAA considers that this rule is necessary to ensure that the unsafe condition is addressed in the event that any of these subject airplanes are imported and placed on the U.S. Register in the future.

Should an affected airplane be imported and placed on the U.S. Register in the future, it would require approximately 4.6 work hours to accomplish the required actions, at an average labor charge of $60 per work hour. The cost of required parts would be negligible. Based on these figures, the cost impact of this AD would be $276 per airplane.

Determination of Rule's Effective Date

Since this AD action does not affect any airplane that is currently on the U.S. register, it has no adverse economic impact and imposes no additional burden on any person. Therefore, notice and public procedures hereon are unnecessary and the amendment may be made effective in less than 30 days after publication in the Federal Register.

Comments Invited

Although this action is in the form of a final rule and was not preceded by notice and opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 96–NM–132–AD.'' The postcard will be date stamped and returned to the commenter.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

96–14–08 Fokker: Amendment 39–9692. Docket 96–NM–132–AD.

Applicability: Model F28 Mark 0100 series airplanes; serial numbers 11244 through 11256 inclusive, 11259, 11260, and 11268 through 11273 inclusive; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent erroneous indications and failure of the AFCAS to properly align, flare, and retard the airplane during autoland operations when a single radio altimeter fails, accomplish the following:

(a) Within 6 months after the effective date of this AD, modify the radio altimeter wiring circuitry (AFCAS data-control jumper) in accordance with Fokker Service Bulletin SBF100–34–015, Revision 2, dated November 27, 1990.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance or Avionics Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM–113.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(d) The modification shall be done in accordance with Fokker Service Bulletin SBF100–34–015, Revision 2, dated November 27, 1990, which contains the following list of effective pages:

Page number	Revision level shown on page	Date shown on page
1, 5	2	November 27, 1990
2–4, 6–9	1	May 16, 1990

This 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 obtained from Fokker Aircraft USA, Inc., 1199 North Fairfax Street, Alexandria, Virginia 22314. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on July 24,1996.

Issued in Renton, Washington, on July 1, 1996.

S.R. Miller,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–17219 Filed 7–8–96; 8:45 am]

BILLING CODE 4910–13–P

14 CFR Part 39

[Docket No. 95–NM–254–AD; Amendment 39–9686; AD 96–14–04]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model DC–10 and MD–11 Series Airplanes, and KC–10A (Military) Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain McDonnell Douglas Model DC–10 and MD–11 series airplanes, and KC–10A (military) airplanes, that requires identifying and replacing certain lock link bolts in the nose landing gear (NLG). This amendment is prompted by a report indicating that certain bolts were improperly heat-treated during manufacturing, which makes them prone to failure. The actions specified by this AD are intended to prevent failure of the lock link bolts in the NLG, which could result in the collapse of the NLG.

DATES: Effective August 13, 1996.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of August 13, 1996.

ADDRESSES: The service information referenced in this AD may be obtained from McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Department C1–L51 (2–60). This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, Transport Airplane Directorate, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Wahib Mina, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712; telephone (310) 627–5324; fax (310) 627–5210.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain McDonnell Douglas Model DC–10 and MD–11 series airplanes, and KC–10A (military) airplanes was published in the Federal Register on March 18, 1996 (61 FR 10907). That action proposed to require a one-time visual inspection to identify suspect lock link bolts, and the replacement of those bolts with new serviceable bolts.

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

Support for the Proposal

Four commenters support the proposal.

Request To Allow Records Search in Lieu of Inspection

One commenter requests that the proposed rule be revised to allow operators to conduct a records search to determine if airplanes are equipped with the suspect bolt, rather than conduct an inspection of every airplane in order to determine if the bolt is installed. This commenter states that, for some operators, the NLG lock link bolts are required to have a tracking history (i.e., records track the bolt by serial number). For these operators, it would be more economically feasible, and just as productive, to conduct a records search in lieu of an inspection.

The FAA concurs. Paragraph (a) of the final rule has been revised to provide for the option of conducting a records search.

Request To Extend the Compliance Time for Replacement

Several commenters request that the proposed rule be revised to allow operators to replace suspect bolts at a later time. These commenters request that, instead of requiring that a suspect bolt be replaced prior to further flight after the inspection is accomplished, the proposed rule should permit operators to replace the bolt at any time after the inspection, but prior to the end of the 24-month compliance time. These commenters consider that this extension of the replacement time will obtain the same result as intended by the FAA, and will have a less disruptive impact on operators' schedules.

The FAA concurs that the bolts need not be replaced prior to further flight after the inspection (or records search) is accomplished. The FAA makes this finding based on the following data pertinent to the configuration of the suspect bolts themselves:

1. None of the suspect bolts were manufactured prior the initial production of the Model MD–11 series airplanes (in 1991). In light of this, the FAA is confident that none of the suspect bolts was installed as original equipment on any of the affected Model DC–10 series airplanes. (Model DC–10's have been produced since 1971.)

2. The suspect bolts were manufactured using a process that did not affect their static strength requirement, but did reduce their fatigue life. These bolts should have a fatigue life in the range of 58,281 landings; due to the manufacturing process used, however, the fatigue life

of the suspect bolts has been reduced to approximately 24,638 landings.

3. A review of the utilization rates of the current worldwide fleet indicates that the highest number of landings accumulated on any Model MD–11 series airplane is approximately 5,000 landings.

4. The average annual utilization rate of the airplanes affected by this AD is between 1,000 and 1,200 landings.

These data indicate that, if any suspect bolt had been installed as original equipment on a Model MD–11 (even those airplanes with the highest number of landings accumulated so far), or installed as a replacement component on a Model DC–10, the fatigue life ''remaining'' on any suspect bolt is long enough to permit continued use of that bolt for a 24-month period.

Based on these factors, the FAA has determined that a large enough margin of safety exists so that replacement of the suspect bolts may be accomplished within 24 months after the effective date of this AD, regardless of when the inspection (or records search) is performed. Paragraph (c) of the final rule has been revised to specify this.

Request To Permit Replacement With Other Than New Bolts

One commenter, the airframe manufacturer, requests that the proposed rule be revised to delete the requirement that a ''new'' bolt be used as a replacement bolt. This commenter states that the use of the term ''new'' excludes the use of refurbished or serviceable bolts that do not have one of the suspect serial numbers.

The FAA concurs. Serviceable (non-suspect) bolts are acceptable as replacement parts. Accordingly, paragraph (c) of the final rule has been revised to delete the word ''new'' from the description of required replacement bolts.

Request To Ensure Availability of Replacement Parts

One commenter expresses concerns that the replacement bolts will not be available in a timely manner. This commenter states that several service bulletins recently have been released by McDonnell Douglas that recommend inspections and replacement of high-strength landing gear parts that were improperly heat-treated. This commenter is concerned that the bolt suppliers may not be able to meet the concurrent demand for the large quantity of parts needed for the entire affected fleet.

The FAA acknowledges this commenters concerns, and just recently contacted the manufacturer on this very subject. The manufacturer has assured the FAA that its suppliers stand ready to meet the demand for parts for the total fleet.

Conclusion

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the changes previously described. The FAA has determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Cost Impact

There are approximately 565 Model DC–10 and MD–11 series airplanes and KC–10A (military airplanes) of the affected design in the worldwide fleet. The FAA estimates that 334 airplanes of U.S. registry will be affected by this proposed AD.

It will take approximately .5 work hour per airplane to accomplish either a one-time inspection or a commensurate records search, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be $10,020, or $30 per airplane.

If a suspect lock link bolt is found to be installed on an airplane, its removal and replacement will take approximately 3 work hours to accomplish, at an average labor rate of $60 per work hour. (For operators of Model MD–11 series airplanes, the manufacturer has indicated that it will reimburse operators for certain of these labor costs as a labor credit allowance.) Replacement parts will be supplied by the manufacture at no charge to operators. Based on these figures, the cost impact of the replacement action on U.S. operators is estimated to be $180 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

96–14–04 McDonnell Douglas: Amendment 39–9686. Docket 95–NM–254–AD.

Applicability: Model DC–10–10, –15, –30, and –40 series airplanes, and KC–10A airplanes, as listed in McDonnell Douglas Service Bulletin DC10–32–242, dated November 1, 1995; and Model MD–11 series airplanes as listed in McDonnell Douglas Service Bulletin MD11–32–060, dated November 6, 1995; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent collapse of the nose landing gear as a result of failure of the lock link bolt, accomplish the following:

(a) Within 24 months after the effective date of this AD, perform either a visual inspection or a records search to determine the serial number of the lock link bolt, part number (P/N) ACG7079–1, installed in the nose landing gear (NLG). If the visual inspection is accomplished, it must be conducted in accordance with procedures specified in McDonnell Douglas Service Bulletin DC10–32–242, dated November 1, 1995, for Model DC–10 series airplanes; or McDonnell Douglas Service Bulletin MD11–32–060, dated November 6, 1995, for Model MD–11 series airplanes.

(b) If the serial number of the lock link bolt is not AP001 through AP036 inclusive, or AP200 through AP344 inclusive: No further action is required by this AD.

(c) If the serial number of the lock link bolt is AP001 through AP036 inclusive, or AP200 through AP344 inclusive: Within 24 months after the effective date of this AD, replace the lock link bolt with a bolt, P/N ACG7079–1, that does not have one of those serial numbers.

(d) As of the effective date of this AD, no person shall install a lock link bolt, part number (P/N) ACG7079–1, having a serial number of AP001 through AP036 inclusive, or AP200 through AP344 inclusive, on any airplane.

(e) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

(f) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(g) The inspection shall be done in accordance with McDonnell Douglas Service Bulletin DC10–32–242, dated November 1, 1995, for Model DC–10 series airplanes; and McDonnell Douglas Service Bulletin MD11–32–060, dated November 6, 1995, for Model MD–11 series airplanes. This 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 obtained from McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Department C1–L51 (2–60). Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, Transport Airplane Directorate, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(h) This amendment becomes effective on August 13, 1996.

Issued in Renton, Washington, on June 27, 1996.

S.R. Miller,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–16951 Filed 7–8–96; 8:45 am]

BILLING CODE 4910–13–P

14 CFR Part 39

[Docket No. 96–NM–133–AD; Amendment 39–9691; AD 96–14–07]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model MD–11 and MD–11F Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to certain McDonnell Douglas Model MD–11 and MD–11F series airplanes, that currently requires repetitive inspections of the tail tank fuel pipe assembly and the associated mounting brackets in the aft fuselage compartment, and follow-on actions, if necessary. That AD also provides for an optional terminating modification for the repetitive inspections. This amendment deletes the optional terminating modification, and expands the applicability of the existing AD to include additional airplanes. This amendment is prompted by reports of cracking or bending of the fuel pipe mounting support and/or attaching bracket in the aft fuselage compartment due to a fuel pressure surge that caused repetitive loading of this area. The actions specified in this AD are intended to prevent such cracking/bending, which could expose the fuel pipe coupling O-ring. An exposed O-ring could lose its sealing effect and could allow a fuel leak in the aft fuselage compartment, which may result in a possible in-flight or ground fire.

DATES: Effective July 24, 1996.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 24, 1996.

Comments for inclusion in the Rules Docket must be received on or before September 9, 1996.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 96–NM–133–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

The service information referenced in this AD may be obtained from McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Department C1–L51 (2–60). This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, Transport Airplane Directorate, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Raymond Vakili, Aerospace Engineer, Propulsion Branch, ANM–140L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712; telephone (310) 627–5262; fax (310) 627–5210.

SUPPLEMENTARY INFORMATION: On November 4, 1991, the FAA issued AD 91–24–09, amendment 39–8095 (56 FR 61364, December 3, 1991), applicable to certain McDonnell Douglas Model MD–11 and MD–11F series airplanes. That AD requires repetitive visual inspections of the tail tank fuel pipe assembly and the associated mounting brackets located in the aft fuselage compartment to verify the correct position of the pipe flange and to detect damaged brackets. It also requires various follow-on actions, if any discrepancy is detected. That AD also provides for an optional terminating modification for the repetitive inspections. That action was prompted by a report of an uncontained fuel leak in the aft fuselage compartment on an in-service airplane, which was the result of migration of the tail tank fuel pipe assembly, and consequent exposure of the O-ring that provides the seal between the pipe assembly and the coupling shroud assembly. The actions required by that AD are intended to prevent a fuel leak in the aft fuselage compartment area, and the possibility of an in-flight or ground fire.

Actions Since Issuance of Previous Rule

Since the issuance of that AD, the FAA has received several reports of cracking or bending of the fuel pipe mounting support and/or attaching bracket at station Y=2033.750 in the aft

fuselage compartment on McDonnell Douglas Model MD–11 series airplanes. A section of the fuel pipe assembly and support bracket of some of these airplanes had been replaced in accordance with the optional terminating modification specified in AD 91–24–09. Additionally, this replacement had been accomplished during production on certain other airplanes on which these incidents occurred.

Investigation revealed that a fuel pressure surge during transfer of the tail tank fuel caused repetitive loading of the fuel pipe mounting support and/or attaching bracket, which resulted in the subject cracking/bending. Although none of the reported events have resulted in a fuel leak in the aft fuselage compartment, the FAA has determined that severe deformation of the bracket could allow the pipe to migrate, which could also expose the O-ring that provides the seal between the fuel pipe and coupling. If the O-ring is exposed, it could lose its sealing effect, and allow a fuel leak in the aft fuselage compartment, which could result in a possible in-flight or ground fire.

In light of these recent incidents, which are similar to the incident that prompted the issuance of AD 91–24–09, the FAA finds that the optional and on-condition terminating modifications (i.e., replacement of a section of the fuel pipe assembly and support bracket, an FAA-approved repair procedure, and replacement of the shroud assembly) specified in AD 91–24–09 do not adequately preclude the addressed unsafe condition identified as in-flight or ground fire. Therefore, the FAA finds that repetitive visual inspections to detect discrepancies (i.e., cracks, or deformation) of the fuel pipe of the fuel transfer system of the tail tank and associated mounting bracket located in the aft fuselage compartment, and to verify the correct position of the fuel pipe flange are necessary. These actions will ensure that the unsafe condition presented by fuel surge during transfer of tail tank fuel is corrected, and provide an acceptable level of safety.

Explanation of Relevant Service Information

The FAA has reviewed and approved McDonnell Douglas Alert Service Bulletin MD11–28A082, dated May 14, 1996. The alert service bulletin describes procedures for repetitive visual inspections to detect discrepancies (i.e., cracks, or deformation) of the fuel pipe of the fuel transfer system of the tail tank and associated mounting bracket located in the aft fuselage compartment; and to verify the correct position of the fuel pipe flange, and various follow-on actions. These follow-on actions include replacing the O-ring, repositioning the tail tank fuel pipe, and installing a temporary phenolic support block assembly. Installation of a phenolic support block assembly between the tail tank fuel pipe and adjoining structure as a temporary restraint will minimize the possibility of migration of the tail tank fuel pipe.

In addition, the visual inspections and certain of the follow-on actions of Alert Service Bulletin MD11–28A082 are essentially identical to those described in McDonnell Douglas MD–11 Alert Service Bulletin A28–22, Revision 4, dated September 16, 1991 (which was referenced in AD 91–24–09). However, the effectivity listing of Alert Service Bulletin MD11–28A082 includes additional airplanes that were not included in the effectivity listing of Alert Service Bulletin A28–22. These additional airplanes have been found to be subject to the addressed unsafe condition.

Explanation of Requirements of Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of this same type design, this AD supersedes AD 91–24–09 to require repetitive visual inspections to detect discrepancies (i.e., cracks or deformation) of the fuel pipe of the fuel transfer system of the tail tank and associated mounting bracket located in the aft fuselage compartment and to verify the correct position of the fuel pipe flange, and various follow-on actions. This AD also expands the applicability of the existing AD to include additional airplanes.

This is considered to be interim action. The manufacturer has advised that it currently is developing a modification that will positively address the unsafe condition addressed by this AD. Once this modification is developed, approved, and available, the FAA may consider additional rulemaking.

Determination of Rule's Effective Date

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 96–NM–133–AD.'' The postcard will be date stamped and returned to the commenter.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a ''significant regulatory action'' under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory

Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–8095 (56 FR 61364, December 3, 1991), and by adding a new airworthiness directive (AD), amendment 39–9691, to read as follows:

96–14–07 McDonnell Douglas: Amendment 39–9691, Docket 96–NM–133–AD. Supersedes AD 91–24–09, Amendment 39–8095.

Applicability: Model MD–11 and MD–11F series airplanes, manufacturer's fuselage numbers 0447 through 0599 inclusive; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent the possibility of an in-flight or ground fire due to fuel leaking from the fuel pipe coupling, accomplish the following:

(a) Perform a visual inspection to detect discrepancies (i.e., cracks or deformation) of the fuel pipe of the fuel transfer system of the tail tank and associated mounting bracket located in the aft fuselage compartment; and to verify the correct position of the fuel pipe flange, in accordance with McDonnell Douglas Alert Service Bulletin MD11–28A082, dated May 14, 1996; at the time specified in paragraph (a)(1) or (a)(2) of this AD, as applicable.

(1) For airplanes on which the modification specified in McDonnell Douglas Service Bulletin 28–22, dated September 24, 1991, has been accomplished; or that have been repaired in accordance with an FAA-approved repair procedure, as specified in paragraph (a)(3) of AD 91–24–09, amendment 39–8095; or on which the shroud assembly has been replaced with a serviceable part: Prior to the accumulation of 600 flight hours, or within 60 days after the effective date of this AD, whichever occurs later.

(2) For airplanes on which the modification specified in McDonnell Douglas Service Bulletin 28–22, dated September 24, 1991, has not been accomplished: Prior to the accumulation of 600 flight hours, or within 60 days since accomplishment of the last visual inspection in accordance with AD 91–24–09, whichever occurs first.

(b) *CONDITION 1.* If no discrepancy is detected during any visual inspection required by paragraph (a) of this AD, accomplish either paragraph (b)(1) or (b)(2) of this AD.

(1) *OPTION 1.* Repeat the visual inspection required by paragraph (a) of this AD thereafter at intervals not to exceed 600 flight hours or 60 days, whichever occurs later. Or

(2) *OPTION 2.* Prior to further flight, install a temporary phenolic support block assembly, shim, clamp, and bracket between the tail tank fuel pipe and station Y=2033.750 bulkhead, in accordance with Condition 1, Option 2, of McDonnell Douglas Alert Service Bulletin MD11–28A082, dated May 14, 1996. Within 6 months after accomplishment of this installation, perform a one-time inspection to verify the correct position of the temporary support block assembly installation in accordance with Figure 2 (Sheet 2 of 3) of the alert service bulletin.

(i) If the assembly is found to be positioned properly, repeat the verification of the correct position of the fuel pipe flange, as specified in paragraph (a) of this AD, thereafter at intervals not to exceed 15 months.

(ii) If the assembly is found to be improperly positioned, prior to further flight, reposition the fuel pipe in accordance with Figure 2 (Sheet 2 of 3) of the alert service bulletin. Repeat the verification of the correct position of the fuel pipe flange, as specified in paragraph (a) of this AD, thereafter at intervals not to exceed 15 months.

(c) *CONDITION 2.* If any discrepancy is detected, and the fuel pipe is found to be improperly positioned, but the O-ring is not exposed, during any visual inspection required by paragraph (a) of this AD, prior to further flight, accomplish either paragraph (c)(1) or (c)(2) of this AD.

(1) *OPTION 1.* Repeat the visual inspection in paragraph (a) of this AD thereafter at intervals not to exceed 600 flight hours or 60 days, whichever occurs later. Or

(2) *OPTION 2.* Prior to further flight, install a temporary phenolic support block assembly, shim, clamp, and bracket between the tail tank fuel pipe and station Y=2033.750 bulkhead; and reposition the fuel pipe assembly, as applicable; in accordance with Condition 2, Option 2, of McDonnell Douglas Alert Service Bulletin MD11–28A082, dated May 14, 1996. Within 6 months after accomplishment of this installation, perform a one-time inspection to verify the correct position of the temporary support block assembly installation in accordance with Figure 2 (Sheet 2 of 3) of the alert service bulletin.

(i) If the assembly is found to be positioned properly, repeat the verification of the correct position of the fuel pipe flange, as specified in paragraph (a) of this AD, thereafter at intervals not to exceed 15 months.

(ii) If the assembly is found to be improperly positioned, prior to further flight, reposition the fuel pipe in accordance with Figure 2 (Sheet 2 of 3) of the alert service bulletin. Repeat the verification of the correct position of the fuel pipe flange, as specified in paragraph (a) of this AD, thereafter at intervals not to exceed 15 months.

(d) *CONDITION 3.* If any discrepancy is detected, and the fuel pipe is found to be improperly positioned, and the O-ring is exposed, during any visual inspection required by paragraph (a) of this AD, prior to further flight, replace the O-ring with a new O-ring, and install a temporary phenolic support block assembly, shim, clamp, and bracket between the tail tank fuel pipe and station Y=2033.750 bulkhead, in accordance with McDonnell Douglas Alert Service Bulletin MD11–28A082, dated May 14, 1996. Within 6 months after accomplishment of the replacement and installation, perform a one-time inspection to verify the correct position of the temporary support block assembly installation in accordance with Figure 2 (Sheet 2 of 3) of the alert service bulletin.

(1) If the assembly is found to be positioned properly, repeat the verification of the correct position of the fuel pipe flange, as specified in paragraph (a) of this AD, thereafter at intervals not to exceed 15 months.

(2) If the assembly is found to be improperly positioned, prior to further flight, reposition the fuel pipe in accordance with Figure 2 (Sheet 2 of 3) of the alert service bulletin. Repeat the verification of the correct position of the fuel pipe flange, as specified in paragraph (a) of this AD, thereafter at intervals not to exceed 15 months.

(e) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

(f) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(g) The actions shall be done in accordance with McDonnell Douglas Alert Service

Bulletin MD11–28A082, dated May 14, 1996. This 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 obtained from McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Department C1–L51 (2–60). Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, Transport Airplane Directorate, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(h) This amendment becomes effective on July 24, 1996.

Issued in Renton, Washington, on July 1, 1996.

S.R. Miller,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–17217 Filed 7–8–96; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

Animal Drugs, Feeds, and Related Products; Chlortetracycline

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 five supplemental new animal drug applications (NADA's) filed by Hoffmann-LaRoche, Inc., Pfizer, Inc., ALPHARMA, Inc., ADM Animal Health & Nutrition Div., and PennField Oil Co. The supplemental NADA's provide for the safe and effective use of Type A medicated articles containing chlortetracycline (CTC) in the feed of chickens, turkeys, swine, sheep, and calves, beef and nonlactating dairy cattle for improved production efficiency and for control and treatment of certain bacterial diseases susceptible to CTC. The approvals reflect compliance with results of the National Academy of Sciences/National Research Council (NAS/NRC), Drug Efficacy Study Group's (DESI) evaluation of the drug's effectiveness, and FDA's conclusions concerning that evaluation.

EFFECTIVE DATE: July 9, 1996.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1623.

SUPPLEMENTARY INFORMATION: The following sponsors have submitted supplements to their approved NADA's:

- Hoffmann-LaRoche, Inc., Nutley, NJ 07110 (formerly held by American Cyanamid Co.), to NADA 48–761, which covers the Type A medicated articles: Aureomix® 293 (50 grams of chlortetracycline hydrochloride per pound (g CTC HCl/lb)) and Aureomycin® 50, 70, 80, 90, and 100 (contain CTC calcium complex equivalent to the indicated g/lb concentrations of CTC HCl);
- Pfizer, Inc., 235 East 42d St., New York, NY 10017, to NADA 92–286, which covers the Type A medicated articles CLTC® 10, 20, 30, 50, and 70 (contain CTC calcium complex equivalent to the indicated g/lb concentrations of CTC HCl) and to NADA 92–287, which covers the Type A medicated articles CLTC® 50 MR and 100 MR (contain CTC calcium complex equivalent to the indicated g/lb concentrations of CTC HCl);
- ALPHARMA, Inc. (formerly A. L. Laboratories), One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, to NADA 46–699, which covers the Type A medicated articles: CTC 100 MR (100 g CTC HCl/lb) and CTC 10, CTC 50, CTC 65, CTC 70, and Micro CTC 100 (contains CTC calcium complex equivalent to the indicated g/lb concentrations of CTC HCl);
- ADM Animal Health & Nutrition Div., P.O. Box 2508, Fort Wayne, IN 46801–2508 (formerly Feed Specialties Co., Inc.), to NADA 48–480, which covers the Type A medicated article Chloratet™ 50 (contains CTC calcium complex equivalent to 50 g CTC HCI/lb); and
- PennField Oil Co., 14040 Industrial Rd., Omaha, NE 68137, to NADA 138–935, which covers the Type A medicated articles: Chlortetracycline Premixes 50, 60, 70, 80, 100 (all contain CTC calcium complex equivalent to the indicated g/lb concentrations of CTC HCl), and 100 MR (100 g CTC HCl/lb).

The drug products were the subject of a NAS/NRC DESI evaluation of effectiveness (DESI 0113NV). The findings were published in the Federal Register of July 21, 1970 (35 FR 11646). NAS/NRC evaluated the drug products as probably effective for growth promotion and feed efficiency and for the treatment of animal diseases caused by pathogens sensitive to chlortetracycline. NAS/NRC stated that:

(1) Claims made regarding ''for prevention of'' or ''to prevent'' should be replaced with ''as an aid in the control of'' or ''to aid in the control of''; (2) claims for growth promotion or stimulation are disallowed and claims for faster gains and/or feed efficiency should be stated as ''may result in faster gains and/or improved feed efficiency under appropriate conditions''; (3) each disease claim should be properly qualified as ''appropriate for use in (name of disease) caused by pathogens sensitive to (name of drug)''; if the disease cannot be so qualified the claim must be dropped; (4) claims pertaining to egg production and hatchability should be changed to ''May aid in maintaining egg production and hatchability, under appropriate conditions, by controlling pathogenic microorganisms''; (5) the labels should warn that treated animals must actually be consuming enough medicated water or medicated feed to provide a therapeutic dosage under the conditions that prevail and, as a precaution, state the desired oral dose per unit of animal weight per day for each species as a guide to effective usage of the preparation in drinking water or feed; and (6) effective blood levels are required for each recommended dosage.

FDA concurred with the NAS/NRC findings, interpreting the phrase ''* * * cannot be so qualified * * *'' in above item (3) to mean ''* * * is not supported by adequate data * * *'' FDA reviewed all available effectiveness data of products subject to the evaluation and concluded that the data supported effectiveness for the control and treatment of certain bacterial diseases susceptible to CTC in chickens, turkeys, swine, sheep, calves, and cattle.

The NAS/NRC DESI evaluation is concerned only with the drugs' effectiveness and safety to the treated animal. It does not take into account the safety for food use of food derived from drug-treated animals. Nothing herein will constitute a bar to further proceedings with respect to questions of safety of the drugs or their metabolites in food products derived from treated animals.

The five subject sponsors filed supplements that revised the labeling of their products to comply with the findings of the NAS/NRC review and FDA's conclusions concerning those findings. The supplemental NADA's were approved as of February 16, 1996. The revisions to § 558.128 (21 CFR 558.128) list the NAS/NRC and FDA-approved conditions of use for CTC-containing Type A medicated articles.

Products which comply with the NAS/NRC findings and FDA's conclusions regarding those findings are eligible for copying under the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) (see the eighth in a series of policy letters issued to facilitate implementation of GADPTRA that published in the Federal Register of August 21, 1991 (56 FR 41561). Accordingly, sponsors may now

obtain approval of abbreviated new animal drug applications (ANADA's) for these CTC Type A medicated articles.

FDA has incorporated within § 558.128 a warning against use of CTC feed in veal calves as part of a general effort to distinguish between ruminating calves and preruminating calves based on information indicating that withdrawal periods established in ruminating calves may not be adequate for preruminating calves.

Also, the agency has removed in § 558.128 the use of the fixed combination for chlortetracycline and sulfamethazine to treat beef cattle. FDA has recodified this approval in a separate section (§ 558.140 (21 CFR 558.140)), as has been done for other fixed combinations. In addition, the agency is using this occasion, of the DESI finalization of the CTC Type A medicated articles, to amend those portions of the regulations containing CTC combination feeds (see list in § 558.128(c)(5)) to revise the CTC claim language to make it consistent with the NAS/NRC and FDA-approved conditions of use.

Furthermore, the agency is deleting the citations for CTC in § 510.515 (21 CFR 510.515). Section 510.515 defines antibiotic drugs permitted in feed that were exempt from the requirement of certification. GADPTRA (Pub. L. 100–670) signed on November 16, 1988, removed the requirement for certification of antibiotic drugs for animal use. In fact, in a final rule published in the Federal Register of May 26, 1989 (54 FR 22741), the agency revoked the antibiotic procedural regulations. The published exemption constituted a sanction by the agency for use of the listed antibiotics. With the finalization of the DESI evaluation of the CTC products, the sanction is obsolete. Also, by deleting the CTC listing from § 510.515, the agency is correcting an error introduced when the regulation was published. Our records indicate that concurrent cites to oxytetracycline in § 510.515(b)(7)(i) and (b)(17)(i) were incorrect, as oxytetracycline was not considered a certifiable antibiotic animal drug; therefore, it was incorrectly listed in § 510.515.

In the Federal Register of October 21, 1977 (42 FR 56264), the then Bureau of Veterinary Medicine issued a notice of opportunity for a hearing (NOOH) on a proposal to withdraw approval of certain NADA's listed in § 558.15, for most subtherapeutic uses of tetracycline (CTC and oxytetracycline) in animal feed. The NOOH was issued in response to scientific research suggesting that subtherapeutic use of such drugs has contributed to the pool of antibiotic-resistant pathogenic microorganisms in food animals. Furthermore, research indicated that the drug resistance could be transferred to pathogenic organisms in humans. The NOOH is still pending and approval of these supplements to finalize the DESI review process for CTC Type A medicated articles does not constitute a bar to subsequent action to withdraw approval on the grounds cited in the outstanding NOOH.

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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), these approvals for food-producing animals do not qualify for marketing exclusivity because the supplemental applications do not contain reports of new clinical or field investigations (other than bioequivalence or residue studies) and new human food safety studies (other than bioequivalence or residue studies) essential to the approvals and conducted or sponsored by the applicant.

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

21 CFR Part 510

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

21 CFR Part 558

Animal drugs, Animal feeds.

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 558 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).

§ 510.515 [Amended]

2. Section 510.515 *Animal feeds bearing or containing new animal drugs subject to the provision of section 512(n) of the act* is amended in paragraph (b) by removing and reserving paragraphs (b)(7), (b)(17), (b)(25), and (b)(29); by redesignating paragraphs (b)(10) and (b)(13) as paragraphs (b)(1) and (b)(2); and in the table in paragraph (c) by removing entries 6, 7, and 8 for ''Chlortetracycline.''

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

4. Section 558.55 is amended in the table in paragraph (d)(2) under entries (i), (ii), and (iv) by revising the items for ''Chlortetracycline 100 to 200'' and by adding new items for ''Chlortetracycline 200 to 400'' to read as follows:

§ 558.55 Amprolium.

* * * * *

(d) * * *

(2) * * *

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) * * *				
* *	* *	*	*	*
	Chlortetracycline 100 to 200.	Chickens; development of active immunity to coccidiosis; control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Chlortetracycline 200 to 400.	Chickens; development of active immunity to coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
* *	* *	*	*	*
(ii) * * *				
* *	* *	*	*	*
	Chlortetracycline 100 to 200.	Chickens; prevention of coccidiosis caused by *E. tenella* only; control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Chlortetracycline 200 to 400.	Chickens; prevention of coccidiosis caused by *E. tenella* only; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
* *	* *	*	*	*
(iv) * * *				
* *	* *	*	*	*
	Chlortetracycline 100 to 200.	Chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Chlortetracycline 200 to 400.	Chickens where immunity to coccidiosis is not desired; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
* *	* *	*	*	*

* * * * *

5. Section 558.58 is amended in the table in paragraph (d)(1) by revising entry (iv) for the items ''Chlortetracycline 100 to 200'' and ''Chlortetracycline 200'' to read as follows:

§ 558.58 Amprolium and ethopabate.

* * * * *

(d) * * *

(1) * * *

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
* *	* *	*	*	*
(iv) * * *				
* *	* *	*	*	*
	Chlortetracycline 100 to 200.	For chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Chlortetracycline 200 to 400.	For chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline.	In low calcium feed containing 0.8% dietary calcium and 1.5% sodium sulfate; feed continuously as sole ration for 7 to 14 d; do not feed to chickens producing eggs for human consumption.	
* *	* *	*	*	*

6. Section 558.128 is amended by revising paragraphs (a), (b), and (c)(1); by removing paragraphs (c)(2) and (c)(3); and by redesignating paragraphs (c)(4) and (c)(5) as paragraphs (c)(2) and (c)(3), to read as follows:

§ 558.128 Chlortetracycline.

(a) *Approvals.* Type A medicated articles containing the following concentrations of either chlortetracycline calcium complex equivalent to chlortetracycline hydrochloride or, for products intended for use in milk replacer, chlortetracycline hydrochloride:

(1) 50 to 100 grams per pound to 000004 in § 510.600(c) of this chapter.

(2) 50 to 100 grams per pound to 000069.

(3) 50 to 100 grams per pound to 046573.

(4) 50 grams per pound to 012286.

(5) 50 to 100 grams per pound to 053389 .

(b) *Related tolerances.* See § 556.150 of this chapter.

(c)(1) It is used in feeds as follows:

Chlortetracycline amount	Combination	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/ton		1. Chickens; increased rate of weight gain and improved feed efficiency.	Do not feed to chickens producing eggs for human consumption.	000004, 000069, 012286, 046573, 053389
		2. Growing turkeys; increased rate of weight gain and improved feed efficiency.	Do not feed to turkeys producing eggs for human consumption.	do
		3. Growing swine; increased rate of weight gain and improved feed efficiency.		do
(ii) 20 to 50 g/ton		Growing sheep; increased rate of weight gain and improved feed efficiency.		000004, 000069, 046573, 053389.
(iii) 50 to 100 g/ton		Swine; reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group *E. Streptococci* susceptible to chlortetracycline.		000004, 000069, 012286, 046573, 053389
(iv) 100 to 200 g/ton		Chickens; control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption.	do

Chlortetracycline amount	Combination	Indications for use	Limitations	Sponsor
(v) 200 g/ton		Turkeys; control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.	do
(vi) 200 to 400 g/ton		1. Chickens; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline.	Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption.	do
		2. Ducks; control and treatment of fowl cholera caused by *Pasteurella multocida* susceptible to chlortetracycline.	Feed in complete ration to provide from 8 to 28 milligrams per pound of body weight per day depending upon age and severity of disease, for not more than 21 d.	000004
(vii) 400 g/ton		1. Turkeys; control of hexamitiasis caused by *Hexamita meleagrides* susceptible to chlortetracycline.	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.	000004, 000069, 012286, 046573, 053389
		2. Turkey poults not over 4 weeks of age; reduction of mortality due to paratyphoid caused by *Salmonella typhimurium* susceptible to chlortetracycline.		do
		3. Breeding swine; control of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to chlortetracycline.	Feed continuously for not more than 14 d.	do
(viii) 500 g/ton		Chickens; reduction of mortality due to *E. coli* infections susceptible to chlortetracycline.	Feed for 5 d; do not feed to chickens producing eggs for human consumption; withdraw 24 h prior to slaughter.	do
(ix)10 mg/g of finished feed daily.		Psittacine birds (cockatoos, macaws, and parrots) suspected or known to be infected with psittacosis caused by *Chlamydia psittaci* sensitive to chlortetracycline.	Feed continuously for 45 d; each bird should consume daily an amount of medicated feed equal to one fifth of its body weight. *Warning:* ''Psittacosis, avian chlamydiosis, or ornithosis is a reportable communicable disease, transmissible between wild and domestic birds, other animals, and man. Contact appropriate public health and regulatory officials.''	00004
(x) 0.1 mg/lb of body weight daily.		Calves (up to 250 lb); for increased rate of weight gain and improved feed efficiency.	In milk replacers or starter feed; include on labeling the warning: ''A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.''	000004, 000069, 012286, 046573, 053389
(xi) 0.5 mg/lb of body weight daily.		Beef cattle (over 700 lb); control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.	Withdraw 48 h prior to slaughter.	do
(xii) 10 mg/lb of body weight		1. Calves, beef and nonlactating dairy cattle; treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline.	Treat for not more than 5 d; in feed excluding milk replacers; withdraw 10 d prior to slaughter except for 24 h for sponsor 046573; include on labeling the warning: ''A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.''	do

Chlortetracycline amount	Combination	Indications for use	Limitations	Sponsor
		2. Calves (up to 250 lb); treatment of bacterial enteritis caused by *E. coli* susceptible to chlortetracycline.	In milk replacers or starter feed; include on labeling the warning: ''A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.''	
		3. Swine; treatment of bacterial enteritis caused by *E. coli* and *S. choleraesuis* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline.	Feed for not more than 14 d; withdraw 5 d prior to slaughter for sponsor 012286.	000004, 000069, 012286, 046573, 053389
(xiii) 25 mg/lb of body weight		Turkeys; control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to chlortetracycline.	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.	do
(xiv) 25 to 70 mg/head/day		Calves (250 to 400 lb); increased rate of weight gain and improved feed efficiency.	Include on labeling the warning: ''A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.''	000004, 000069, 012286, 046573, 053389
(xv) 70 mg/head/day		Growing cattle (over 400 lb) increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses.	do	do
(xvi) 80 mg/head/day		Breeding sheep; reducing the incidence of (vibrionic) abortion caused by *Campylobacter fetus* infection susceptible to chlortetracycline.		000004, 000069, 046573, 053389
(xvii) 350 mg/head/day		1. Cattle (under 700 lb); control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline.	Withdraw 48 h prior to slaughter.	000004, 000069, 012286, 046573, 053389
		2. Beef cattle (under 700 lb); control of active infection of anaplasmosis caused by *A. marginale* susceptible to chlortetracycline.	do	do

* * * * *

7. New § 558.140 is added to subpart B to read as follows:

§ 558.140 Chlortetracycline and sulfamethazine.

(a) *Approvals.* Type A medicated articles: 35 grams of chlortetracycline per pound with 7.7 percent (35 grams) of sulfamethazine to 000004 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See §§ 556.150 and 556.670 of this chapter.

(c) It is used in feed for beef cattle as follows:

(1) *Amount per head per day.* Chlortetracycline, 350 milligrams plus sulfamethazine, 350 milligrams.

(2) *Indications for use.* Aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever.

(3) *Limitations.* Feed for 28 days; withdraw 7 days prior to slaughter.

8. Section 558.175 is amended by revising paragraph (c)(2)(ii) to read as follows:

§ 558.175 Clopidol.

* * * * *

(c) * * *

(2) * * *

(ii) *Amount per ton.* Clopidol, 113.5 grams (0.0125 percent) plus chlortetracycline 100 to 200 grams.

(*a*) *Indications for use.* Aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix,* E. *acervulina, E. maxima, E. brunetti,* and *E. mivati*; control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.

(*b*) *Limitations.* Feed continuously as sole ration from the time chicks are placed in floor pens for 7 to 14 days.

* * * * *

9. Section 558.195 is amended in the table in paragraph (d) in the entry for ''27.2 (0.003pct)'' by removing the item for ''Chlortetracycline 200'' and adding in its place an item for ''Chlortetracycline 100 to 200'' and an item for ''Chlortetracycline 200 and 400'' to read as follow:

§ 558.195 Decoquinate.

* * * * *

(d) * * *

Decoquinate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
27.2 (0.003pct)				
* *	*	* *	*	*
	Chlortetracycline 100 to 200.	Chickens; for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. mivati, E. acervulina, E. maxima,* and *E. brunetti*; control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption; in low calcium feed containing 0.8 pct. of calcium; feed continuously 7 to 14 days.	011526
	Chlortetracycline 200 to 400.	Chickens; for the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. mivati , E. acervulina, E. maxima,* and *E. brunetti*; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline.	do	011526
* *	*	* *	*	*

10. Section 558.274 is amended in the table in paragraph (c)(1) under entry (i) by revising the item for ''Chlortetracycline 100 to 200'' and by adding a new item for ''Chlortetracycline 200 to 400''; and under entry (ii) by removing the item for ''Chlortetracycline 100 to 200'' and adding in its place an item for ''Chlortetracycline 400'' to read as follows:

§ 558.274 Hygromycin B.

* * * * *

(c) * * *

(1) * * *

Hygromycin B in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) * * *				
* *	*	* *	*	*
	Chlortetracycline 100 to 200.	Chickens; control of infestation of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*); control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption; feed for 7 to 14 days; withdraw 3 days before slaughter.	
	Chlortetracycline 200 to 400.	Chickens; control of infestation of large roundworms (*Ascaris galli*), cecal worms (*H. Gallinae*), and capillary worms (*Capillaria obsignata*); control of chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to chlortetracycline.	do	
* *	*	* *	*	*
(ii) * * *				

Hygromycin B in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
* *	*	* *	*	*
	Chlortetracycline 400.	Swine; control of infestation of large roundworms (*Ascaris suis*), nodular worms (*Oesophagostomum dentatum*) and whipworms (*Trichuris suis*); treatment of bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline.	Withdraw 15 d before slaughter.	
* *	*	* *	*	*

* * * * *

11. Section 558.515 is amended by revising paragraphs (d)(1)(iii), (d)(1)(iv), and (d)(1)(v)(*b*) to read as follows:

§ 558.515 Robenidine hydrochloride.

* * * * *

(d) * * *

(1) * * *

(iii) *Amount per ton*. Robenidine hydrochloride, 30 grams (0.0033 percent) plus chlortetracycline, 100 to 200 grams.

(*a*) *Indications for use*. As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix*; control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.

(*b*) *Limitations*. Withdraw 5 days prior to slaughter; do not feed to chickens producing eggs for human consumption; feed continuously as sole ration up to 14 days.

(iv) *Amount per ton*. Robenidine hydrochloride, 30 grams (0.0033 percent) plus chlortetracycline, 200 to 400 grams.

(*a*) *Indications for use*. As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E.* necatrix; control of chronic respiratory disease (CRD) and air sac infection caused by M. *gallisepticum* and *E. coli* susceptible to chlortetracycline.

(*b*) *Limitations*. Withdraw 5 days prior to slaughter; do not feed to chickens producing eggs for human consumption; feed continuously as sole ration up to 14 days.

(v) * * *

(*b*) *Limitations*. Withdraw 5 days prior to slaughter; do not feed to chickens producing eggs for human consumption; feed continuously up to 5 days.

* * * * *

12. Section 558.530 is amended by revising paragraph (a); by redesignating paragraphs (d)(2), (d)(3), and (d)(4) as paragraphs (d)(4), (d)(5), and (d)(6), by adding new paragraphs (d)(2) and (d)(3); and by revising newly redesignated paragraph (d)(4) to read as set forth below, and in newly redesignated paragraph (d)(6) by redesignating paragraphs (d)(6)(i)(*a*) through (*d*) as paragraphs (d)(6)(i)(A) through (D).:

§ 558.530 Roxarsone.

(a) *Approvals*. Type A medicated articles: (1) 10, 20, and 50 percent to 011526 in § 510.600(c) of this chapter for use as in paragraph (d)(1) of this section.

(2) 10, 20, 50, and 80 percent to 046573 in § 510.600(c) of this chapter for use as in paragraphs (d)(1), (d)(2), (d)(3), and (d)(4) of this section.

* * * * *

(d) * * *

(2) *Growing chickens*—(i) *Grams per ton*. Roxarsone, 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 10 to 50.

(A) *Indications for use*. For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(B) *Limitations*. Do not feed to chickens producing eggs for human consumption; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness; feed continuously throughout growing period.

(ii) *Grams per ton*. Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 100 to 200.

(A) *Indications for use*. For increased rate of weight gain, improved feed efficiency, and improved pigmentation; control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.

(B) *Limitations*. See paragraph (d)(2)(i)(B) of this section except feed continuously for 7 to 14 days.

(iii) *Grams per ton*. Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 200 to 400.

(A) *Indications for use*. For increased rate of weight gain, improved feed efficiency, and improved pigmentation; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *Escherichia coli* susceptible to chlortetracycline.

(B) *Limitations*. See paragraph (d)(2)(i)(B) of this section except feed continuously for 7 to 14 days.

(iv) *Grams per ton*. Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 500.

(A) *Indications for use*. For increased rate of weight gain, improved feed efficiency, and improved pigmentation; reduction of mortality due to *E. coli* infections susceptible to chlortetracycline.

(B) *Limitations*. See paragraph (d)(2)(i)(B) of this section except feed for 5 days.

(3) *Growing turkeys*—(i) *Grams per ton*. Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 10 to 50.

(A) *Indications for use*. For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(B) *Limitations*. Do not feed to turkeys producing eggs for human consumption; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness; feed continuously throughout growing season.

(ii) *Grams per ton*. Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline 200.

(A) *Indications for use*. For increased rate of weight gain, improved feed efficiency, and improved pigmentation; control of infectious synovitis caused by

M. synoviae susceptible to chlortetracycline.

(B) *Limitations.* See paragraph (d)(3)(i)(B) of this section except that the drug should only be fed continuously for 7 to 14 days.

(iii) *Grams per ton.* Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 400.

(A) *Indications for use.* For increased rate of weight gain, improved feed efficiency, and improved pigmentation; control of hexamitiasis caused by *Hexamita meleagrides* susceptible to chlortetracycline. Turkey poults not over 4 weeks of age: Reduction of mortality due to paratyphoid caused by *Salmonella typhimurium* susceptible to chlortetracycline.

(B) *Limitations.* See paragraph (d)(3)(i)(B) of this section except that the drug should only be fed continuously for 7 to 14 days.

(iv) *Amount.* Roxarsone 22.7 to 45.4 grams per ton (0.0025 to 0.005 percent) plus chlortetracycline, 25 milligrams per pound of body weight daily.

(A) *Indications for use.* For increased rate of weight gain, improved feed efficiency, and improved pigmentation; control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to chlortetracycline.

(B) *Limitations.* See paragraph (d)(3)(i)(B) of this section except that the drug should only be fed continuously for 7 to 14 days.

(4) *Growing-finishing swine*—(i) *Grams per ton.* Roxarsone 22.7 to 34.1 (0.0025 to 0.00375 percent).

(A) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* Withdraw 5 days before slaughter; as sole source of organic arsenic; feed continuously throughout growing season.

(ii) *Grams per ton.* Roxarsone 22.7 to 34.1 (0.0025 to 0.00375 percent) plus chlortetracycline, 400 (to administer 10 milligrams per pound of body weight).

(A) *Indications for use.* For increased rate of weight gain and improved feed efficiency; treatment of bacterial enteritis caused by *E. coli* and *S. choleraesuis* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline.

(B) *Limitations.* Withdraw 5 days before slaughter; as sole source of organic arsenic; feed for not more than 14 days.

(iii) *Grams per ton.* Roxarsone 181.5 (0.02 percent).

(A) *Indications for use.* For the treatment of swine dysentery.

(B) *Limitations.* Feed for not more than 6 consecutive days; if improvement is not observed, consult a veterinarian; withdraw 5 days before slaughter; as a sole source or organic arsenic; animals must consume enough medicated feed to provide a therapeutic dose.

(iv) *Grams per ton.* Roxarsone, 181.5 (0.02 percent) plus chlortetracycline, 10 to 50.

(A) *Indications for use.* For the treatment of swine dysentery; increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* See paragraph (d)(4)(iii)(B) of this section.

(v) *Grams per ton.* Roxarsone, 181.5 (0.02 percent) plus chlortetracycline, 400.

(A) *Indications for use.* For the treatment of swine dysentery; treatment of bacterial enteritis caused by *E. coli* and *S. choleraesuis* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline.

(B) *Limitations.* See paragraph (d)(4)(iii)(B) of this section.

* * * * *

13. Section 558.680 is amended in the table in paragraph (c)(1) under entries (i) and (ii) by revising the item for ''Chlortetracycline 100 to 200''; by removing the item for ''Chlortetracycline 200'' and adding in its place an item for ''Chlortetracycline 200 to 400'' to read as follows:

§ 558.680 Zoalene.

* * * * *

(c) * * *

(1) * * *

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations
(i) * * *			
* *	*	* *	* *
	Chlortetracycline 100 to 200.	Replacement chickens; development of active immunity to coccidiosis; control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
	Chlortetracycline 200 to 400.	Replacement chickens; development of active immunity to coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *Escherichia coli* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
* *	*	* *	* *
(ii) * * *			
* *	*	* *	* *
	Chlortetracycline 100 to 200	Broiler chickens; prevention and control of coccidiosis; control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption; feed continuously for 7 to 14 d.

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations
	Chlortetracycline 200 to 400	Broiler chickens; prevention and control of coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption; feed continuously for 7 to 14 d.
* *	*	* *	* *

* * * * *

Dated: June 13, 1996.

Andrew J. Beaulieau,

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

[FR Doc. 96–17169 Filed 7–8–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 941

[Docket No. FR–3919–N–04]

Office of the Assistant Secretary for Public and Indian Housing; Public/Private Partnerships for the Mixed-Finance Development of Public Housing Units Extension of Public Comment Deadline on Interim Rule

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice of Extension of Public Comment Deadline on Interim Rule.

SUMMARY: On May 2, 1996, HUD published an interim rule that added a new subpart F to the public housing development program at 24 CFR part 941. Under this new subpart, a public housing authority (PHA) was authorized to provide to a non-PHA entity public housing development and operating funds for the development and operation of the resulting public housing units. In addition, the rule clarified that replacement public housing units for public housing units that have been demolished could be built on the original public housing site, or in the same neighborhood, if the number of such replacement units was significantly fewer than the number of units demolished. The May 2, 1996 interim rule provided for the public comment period to expire on July 1, 1996. This notice extends the public comment period to September 15, 1996.

DATES: Comment Due Date: September 15, 1996.

ADDRESSES: Interested persons are invited to submit comments on the interim rule to the Office of the General Counsel, Rules Docket Clerk, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410–0500. Communications should refer to the above docket number and title. A copy of each communication submitted will be available for public inspection and copying during regular business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Bill Flood, Office of Capital Improvements, Office of Public and Indian Housing, U.S. Department of Housing and Urban Development, 451 Seventh Street, SW., Room 4134, Washington, DC 20410–0500, telephone (202) 708–1640, ext. 4185; (TTY): (202) 708–9300 or 1–800–877–8339. (Except for the ''800'' telephone number, these are not toll-free numbers.)

SUPPLEMENTARY INFORMATION: On May 2, 1996, HUD published an interim rule (61 FR 19708) that added a new subpart F to the public housing development program at 24 CFR part 941. Under this interim rule, a PHA is authorized to provide a portion of its HUD-awarded development and operating funds to a non-PHA entity for the entity to own, develop and operate the resulting public housing units. The non-PHA entity may develop and operate the public housing units using public and private financing (i.e., as a ''mixed-finance'' project), and to develop solely public housing units or a combination of public housing, shallow subsidy, and market rate units.

In addition, the May 2, 1996 interim rule added a new paragraph (c)(3) to HUD's existing site and neighborhood standards at § 941.202. This purpose of this provision was to clarify HUD's existing authority to approve the building of replacement public housing units for public housing units that have been demolished on either the original public housing site, or in the same neighborhood, if the number of such replacement public housing units is significantly fewer than the number of public housing units demolished. This authority was affirmed by the passage of section 1002(a)(9) of Pub. L. 104–19 (approved July 27, 1995) which explicitly authorized HUD to approve the building of replacement public housing units under such circumstances.

Extension of Public Comment Period

The May 2, 1996 interim rule provided for a 60-day public comment period which is scheduled to close on July 1, 1996. Because of the significant public interest in this rule, HUD is extending the public comment period to September 15, 1996.

Dated: June 28, 1996.

Michael B. Janis,

General Deputy, Assistant Secretary for Public and Indian Housing.

[FR Doc. 96–17177 Filed 7–8–96; 8:45 am]

BILLING CODE 4210–33–M

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972

AGENCY: Department of the Navy, DoD.

ACTION: Final rule.

SUMMARY: The Department of the Navy is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS). The Deputy Assistant Judge Advocate General (Admiralty) of the Navy has determined that a prior certification of noncompliance for USS SEAWOLF (SSN 21) should be amended. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

EFFECTIVE DATE: March 4, 1996.

FOR FURTHER INFORMATION CONTACT: Captain R. R. Pixa, JAGC, U.S. Navy; Admiralty Counsel, Office of the Judge Advocate General Navy Department, 200 Stovall Street, Alexandria, VA 22332–2400, Telephone number: (703) 325–9744.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the Department of the Navy amends 32 CFR Part 706. This amendment provides notice that the Deputy Assistant Judge Advocate General (Admiralty) of the Navy, under authority delegated by the Secretary of the Navy, has determined that certain navigation lights on USS SEAWOLF (SSN 21), previously certified as not in compliance with 72 COLREGS, have been relocated. The relocation has resulted in a reduction in the arc of visibility of the side lights of the vessel from 118.3 degrees to 111.5 degrees.

Moreover, it has been determined, in accordance with 32 CFR Parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine safety, Navigation (water), and Vessels.

Accordingly, 32 CFR Part 706 is amended as follows:

PART 706—[AMENDED]

1. The authority citation for 32 CFR Part 706 continues to read:

Authority: 33 U.S.C. 1605.

2. Table Three of § 706.2 is amended by adding an entry for USS SEAWOLF (SSN 21) to read as follows:

§ 706.2 Certifications of the Secretary of the Navy under Executive Order 11964 and 33 U.S.C. 1605.

* * * * *

TABLE 3

Vessel	No.	Masthead lights arc of visibility; rule 21(a)	Side lights arc of visibility; rule 21(b)	Stern light arc of visibility; rule 21(c)	Side lights distance inboard of ship's sides in meters 3(b) annex 1	Stern light, distance forward of stern in meters; rule 21(c)	Forward anchor light, height above hull in meters; 2(K) annex 1	Anchor lights relationship of aft light to forward light in meters 2(K) annex 1
* *		*	*	*	*	*		*
USS SEAWOLF	SSN–21	225°	111.5°	205°	5.1	10.7	2.8	1.8 below.
* *		*	*	*	*	*		*

Dated: June 4, 1996.

M.W. Kerns,

Lieutenant, JAGC, U.S. Navy, Deputy Assistant Judge Advocate General (Admiralty), Acting.

[FR Doc. 96–16830 Filed 7–8–96; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 222

Management of Wild Free-Roaming Horses and Burros

AGENCY: Forest Service, USDA.

ACTION: Correction.

SUMMARY: The Forest Service is amending regulations for management of wild free-roaming horses and burros to correct a citation that was redesignated when the agency amended regulations for impoundment and disposal of unauthorized livestock. This rulemaking is identified as an agency action under the USDA Regulatory Reform initiative.

EFFECTIVE DATE: This rule is effective July 9, 1996.

FOR FURTHER INFORMATION CONTACT: Ralph Giffen, Range Management Staff, Forest Service, USDA, P.O. 96090, Washington, D.C. 20090–6090, (202) 205–1460.

SUPPLEMENTARY INFORMATION: While reviewing current regulations as part of the President's Regulatory Reform Initiative, an agency review team identified an incorrect citation in the wild horse and burro management regulations. This technical amendment corrects that citation.

On April 9, 1980, at 45 FR 24135, the Secretary of Agriculture established final regulations for the Management of Wild and Free-Roaming Horses and Burros at 36 CFR Part 222, Subpart B. Section 222.23 of that rule cited § 262.2 of the same Title as the authority for the impoundment and removal of unauthorized livestock on National Forest System lands. By issuance of final regulations on June 9, 1983 (48 FR 26605), § 262.2 was redesignated § 262.10. Currently regulations at § 262.10 of Title 36 provide for impoundment and disposal of unauthorized livestock on National Forest System lands. The Forest Service is correcting this citation by amending Title 36 of the Code of Federal Regulations, Part 222, Subpart B.

As a technical amendment, this final rule is not subject to review under Executive Orders 12630, 12778, or 12866.

List of Subjects in 36 CFR Part 222

Grazing lands, Livestock, National forests, National grasslands, Range management, and Wildlife.

Therefore, for the reasons set forth in the preamble, Part 222 of Title 36 of the Code of Federal Regulations is hereby amended as follows:

PART 222—[AMENDED]

Subpart B—Management of Wild Free-Roaming Horses and Burros

1. The authority citation for Subpart B of Part 222 continues to read as follows:

Authority: 85 Stat. 649, as amended 16 U.S.C. 1331–1340); sec. 1, 30 Stat. 35, as amended (16 U.S.C. 551); sec. 32, 50 Stat. 522, as amended (7 U.S.C. 1011); 92 Stat. 1803 (43 U.S.C. 1901 note).

2. Revise section 222.23 to read as follows:

§ 222.23 Removal of other horses and burros.

Horses and burros not within the definition in § 222.20(b)(13) which are

introduced onto Wild Horse and Burro Territories or ranges after December 15, 1971, by accident, negligence, or willful disregard of private ownership, and which do not become intermingled with wild free-roaming horses or burros shall be considered as unauthorized livestock and treated in accordance with provisions in 36 CFR 261.7 and 262.10.

Dated: June 28, 1996.

David G. Unger,

Associate Chief.

[FR Doc. 96–17444 Filed 7–8–96; 8:45 am]

BILLING CODE 3410–11–M

36 CFR Part 223

Sale and Disposal of National Forest System Timber; Subpart E—Federal Timber Contract Payment Modification Program

AGENCY: Forest Service, USDA.

ACTION: Final rule; technical amendment.

SUMMARY: The Forest Service is amending its regulations on timber sale contracts to remove the subpart on Federal timber contract payment modification program. Originally required to implement the Federal Timber Contract Payment Modification Act of 1984, these regulations were reviewed during the regulatory reform phase II initiative of the National Performance Review and determined to be obsolete.

EFFECTIVE DATE: July 9, 1996.

FOR FURTHER INFORMATION CONTACT: Jim Naylor, Timber Management Staff, Forest Service, USDA, P.O. Box 96090, Washington, D.C. 20090–6090, (202) 205–0858.

SUPPLEMENTARY INFORMATION:

Background

The Federal Timber Contract Payment Modification Act of October 16, 1984, (16 U.S.C. 618) authorized and directed the Secretaries of Agriculture and the Interior to release a timber sale purchaser from specified contractual obligations thereby returning to the Government certain timber sale contracts.

Speculative bidding in the early 1980's, followed by a substantial drop in the forest products market, left may timber purchasers in high risk of defaulting timber sale contracts and having to declare bankruptcy.

The Act allowed purchasers of national forest timber to return to the Government a certain number of timber sale contracts upon payment of a ''buy-out charge.''

The final rule to implement the Federal Timber Contract Payment Modification Act was published in the Federal Register on June 27, 1985, at 50 FR 26666. Under this regulation, purchasers were required to apply for contract buyout within 90 days of the published date of the rule. All of the contracts governed by this regulation are closed. Also, the emergency rate redetermination in Alaska rules, which were part of Subpart E, are no longer applicable. Therefore, these rules are no longer needed and by this amendment are removed from the Code of Federal Regulations. Because of the narrow scope and limited effect of this action, the Agency has determined that this amendment is a technical amendment for which notice and comment pursuant to the Administrative Procedures Act (5 U.S.C. 553) is neither practical nor necessary.

Regulatory Impact

This rule is a technical amendment to remove obsolete regulations and, as such, has no substantive effect nor is it subject to review under USDA procedures and Executive Order 12866 on Regulatory Planning and Review. Accordingly, this rule is not subject to OMB review under Executive Order 12866.

Moreover, good cause exists to exempt this rule from notice and comment pursuant to 5 U.S.C. 553 and, therefore, this rule is exempt from further analysis under the Unfunded Mandates Reform Act of 1995; Executive Order 12778, Civil Justice Reform; Executive Order 12630, Takings Implications; or The Paperwork Reduction Act of 1995.

Environmental Impact

This action falls within a category of actions excluded from documentation in an Environmental Impact Statement and an Environmental Assessment. Section 31.1b of Forest Service Handbook 1909.15 (57 FR 43180; September 18, 1992) excludes from documentation in an environmental assessment or impact statement ''rules, regulations, or policies to establish Service-wide administrative procedures, program processes, or instructions.'' The agency's assessment is that this final technical rule falls within this category of actions and that no extraordinary circumstances exist which would require preparation of an environmental assessment or environmental impact statement.

List of Subjects in 36 CFR Part 223

Exports, Government contracts, National forests, Reporting requirements, and Timber sales.

Therefore, for the reasons set forth in the preamble, Part 223 of Title 36 of the Code of Federal Regulations is hereby amended as follows:

PART 223—SALE AND DISPOSAL OF NATIONAL FOREST SYSTEM TIMBER

1. The authority citation for part 223 continues to read as follows:

Authority: 90 Stat. 2958, 16 U.S.C. 472a; 98 Stat. 2213, 16 U.S.C. 618; 104 Stat. 714–726, 16 U.S.C. 620–620h, unless otherwise noted.

Subpart E—[Removed and Reserved]

2. Remove and reserve Subpart E consisting of sections 223.170–223.183.

Dated: June 28, 1996.

David G. Unger,

Associate Chief.

[FR Doc. 96–17443 Filed 7–8–96; 8:45 am]

BILLING CODE 3410–11–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 80

[FRL–5532–6]

RIN 2060–AD27

Regulation of Fuels and Fuel Additives; Standards for Reformulated Gasoline

AGENCY: Environmental Protection Agency (EPA).

ACTION: Petition for reconsideration; request for comment.

SUMMARY: EPA requests comment on a petition submitted to EPA by the American Petroleum Institute (API). The petition, submitted pursuant to section 553(e) of the Administrative Procedure Act, requests reconsideration of the Phase II reformulated gasoline reduction standard for oxides of nitrogen (NO_X).

DATES: Comments must be received on or before September 9, 1996.

ADDRESSES: Interested parties may submit written comments (in triplicate, if possible) to: EPA Air and Radiation Docket, Attention Docket No. A–96–27, room M–1500 (mail code 6102), 401 M St., SW, Washington, D.C. 20460. The docket may be inspected at this location from 8:30 a.m. until 5:30 p.m. weekdays. The docket may also be reached by telephone at (202) 260–7548. As provided in 40 CFR part 2, a reasonable fee may be charged by EPA for photocopying.

FOR FURTHER INFORMATION CONTACT: Debbie Wood, Office of Mobile Sources, Fuels and Energy Division, (202) 233–9000.

SUPPLEMENTARY INFORMATION:

I. Introduction and Background

On February 16, 1994, EPA published a final rule establishing emission reduction and other performance standards for reformulated gasoline (RFG), including provisions for the certification of RFG and enforcement of RFG standards, and establishing certain requirements regarding unreformulated or conventional gasoline (59 FR 7716). The purpose of the RFG program is to improve air quality by requiring that gasoline be reformulated to reduce emissions from motor vehicles of toxics and tropospheric ozone-forming compounds, as specified by section 211(k)(1) of the Clean Air Act (CAA or the Act). Section 211(k) mandates that RFG be sold in the nine largest metropolitan areas with the most severe summertime ozone levels; RFG must also be sold in other ozone nonattainment areas that choose to participate or ''opt in'' to the program. The Act further prohibits conventional gasoline sold in the rest of the country from becoming any more polluting than it was in 1990 by requiring that each refiner's and importer's gasoline be as clean, on average, as it was in 1990; this statutory prohibition has resulted in requirements referred to as the ''anti-dumping'' program.

The Act mandates certain requirements for the RFG program. Section 211(k)(1) directs EPA to issue regulations that:

> * * * require the greatest reduction in emissions of ozone forming volatile organic compounds (during the high ozone season) and emissions of toxic air pollutants (during the entire year) achievable through the reformulation of conventional gasoline, taking into consideration the cost of achieving such emission reductions, any nonair-quality and other air-quality related health and environmental impacts and energy requirements.

Section 211(k)(3) specifies the minimum requirement for reduction of volatile organic compounds (VOC) and toxics for 1995 through 1999, or Phase I of the RFG program; the section specifies that EPA must require the more stringent of a formula fuel or an emission reduction performance standard, measured on a mass basis, equal to 15 percent of baseline emissions. Baseline emissions are the emissions of 1990 model year technology vehicles operated on a specified baseline gasoline. Section 211(k)(2) compositional specifications for RFG include a 2.0 weight percent oxygen minimum and a 1.0 volume percent benzene maximum. Section 211(k)(2) also specifies that NO_X emissions may not increase in RFG.

For the year 2000 and beyond, or Phase II of the RFG program, the Act specifies that the VOC and toxics performance standards must be no less than either a formula fuel or a 25 percent reduction from baseline emissions, whichever is more stringent. EPA can adjust these standards upward or downward taking into account such factors as feasibility and cost, but in no case can they be less than 20 percent.

Shortly after passage of the CAA Amendments in 1990, EPA entered into a regulatory negotiation with interested parties to develop specific proposals for implementing both the RFG and anti-dumping programs. In August 1991, the negotiating committee reached consensus on a program outline, addressing emission content standards for Phase I (1995–2000), emission models, certification, use of averaging and credits, and other important program elements.

The regulatory negotiation conducted by EPA did not, however, address Phase II VOC and toxics standards, nor did it address a reduction in NO_X emissions beyond the statutory cap imposed under section 211(k)(2)(A). The final rule promulgated by EPA closely followed the outline agreed to in the negotiated rulemaking. The final rule also adopted a NO_X reduction performance standard for Phase II RFG, relying on authority under section 211(c)(1)(A).

In proposing and promulgating a NO_X reduction standard, EPA analyzed the costs and benefits, along with other relevant factors, including EPA's view that NO_X reductions are important to achieve attainment of the ozone National Ambient Air Quality Standard (NAAQS) in many nonattainment areas. In the final rule, EPA discussed recent studies which indicate that NO_X control is an effective ozone control strategy for the northeast as well as the Lake Michigan area (59 FR 7751). EPA also noted that there are non-ozone benefits from NO_X control, such as reduced acid rain and improved visibility (59 FR 7751). In considering the feasibility of section 202 motor vehicle controls prior to regulating fuels, EPA cited several reasons for the promulgation of a NO_X reduction standard (59 FR 7752): (1) Significant emission reductions would be achieved right away, in the summer of 2000, with no delay based on fleet turnover time. (2) A NO_X reduction standard for gasoline would act to reduce emissions from all mobile sources that use gasoline, whether on-highway or nonroad. (3) The fuel control is specifically aimed at areas of the country that are in nonattainment for ozone, and is limited in time to that part of the year when ozone is of most concern. (4) The expected increase in vehicle miles traveled over time leads EPA to believe that this fuel control is needed to continue to achieve the in-use NO_X emission reductions necessary for many areas of the country to reach attainment for ozone. (5) The performance standard adopted minimizes any concern that a fuel control could interfere in the production process by directing refiners on how to make their product.

EPA estimates that the Phase II NO_X emission reduction standard of 6.8 percent on average will reduce summertime NO_X emissions from gasoline-powered mobile sources by approximately 22,000 tons annually. Cost-effectiveness is estimated at $5,000 per ton of NO_X reduction.

In December 1995, API submitted a petition to EPA requesting reconsideration of the Phase II RFG NO_X standard or, at a minimum, suspension of the effective date of the standard. API bases its request for reconsideration on three arguments: (1) The standard is inconsistent with the CAA Amendments of 1990 and the 1991 negotiated rulemaking. (2) Air quality benefits of the standard are overstated. (3) The standard is not a cost-effective strategy for ozone control. These arguments were also submitted to EPA by API as comments during the RFG rulemaking; the final rule preamble discusses these arguments and explains EPA's reasons for promulgating the NO_X reduction standard (see 59 FR 7716, 7744–7756).

An initial review of the API petition indicates that it presents no compelling new evidence or argument that would warrant revisiting the decision made in promulgating the Phase II NO_X reduction standard. However, to ensure that our conclusions on the appropriateness of the NO_X reduction standard remain well-founded, EPA will review any relevant and available new information on costs and benefits that has been developed since promulgation of the final rule. EPA solicits comment on the issues raised in the petition. The arguments presented in the API petition are summarized below. A complete copy of the API petition may be found in the docket for this notice.

II. Summary of API Petition

A. Consistency With CAA and Negotiated Rulemaking

API's first argument is that EPA's Phase II RFG NOG5**X** standard is inconsistent with the CAA Amendments of 1990 and the 1991 negotiated rulemaking. API cites provisions of the Act that specifically require reductions in various pollutants, and contrasts that

with the ''no NO_X increase'' approach taken toward RFG in section 211(k). API also notes that the 1991 negotiated rulemaking agreement does not address a Phase II NO_X reduction, and that the focus of debate was whether *de minimis* increases in NO_X would satisfy the no NO_X increase standard. For discussion of these arguments in the RFG final rule, see, for example, 59 FR 7744–7745.

B. Air Quality Benefits

API's second argument is that the ozone benefits of the Phase II RFG NO_X standard are overstated. API argues that the primary basis for the Phase II NO_X standard is ozone attainment, and cites data from EPA's Trends Report (U.S. EPA, National Air Quality and Emissions Trends Report 1993, EPA 454/R–94–026, October 1994 at 6.) that progress toward ozone attainment has been made. API also notes that the Act imposes substantial obligations on states to attain ozone standards.

API claims that in promulgating the Phase II RFG NO_X standard, EPA emphasized those parts of studies (such as Rethinking the Ozone Problem in Urban and Regional Air Pollution, National Research Council, National Academy Press, Washington, D.C. 1991) that showed NO_X to be an effective ozone control strategy, while discounting those which indicate that NO_X control can be counterproductive.

API discusses EPA's authority under CAA section 182 to grant waivers from certain CAA local NO_X reduction requirements. The petition states that the section 182(f) waiver requirement recognizes that local NO_X reductions may not be necessary or helpful to attainment of the ozone standard. Although the overwhelming majority of section 182(f) waivers have been granted because additional NO_X reductions are not needed for attainment of the ozone NAAQS, the petition notes that, in a few cases, photochemical modeling has indicated that increased NO_X reductions may exacerbate peak ozone in an urban core. The petition cites three cases where modeling has shown that increased NO_X reductions may exacerbate peak ozone concentrations: Chicago, Milwaukee, and Houston, three of the nine cities required to use RFG. API notes the conditional nature of section 182(f) waivers.

API argues that given continued progress toward ozone NAAQS attainment, imposition of Phase II NO_X reductions applicable in all RFG areas is ''plainly incongruous'' with the granting of waivers under section 182(f). API also argues that EPA's claim that air quality benefits in addition to reduced ozone will result from the Phase II NO_X standard (e.g., less acid rain, reduced nitrate deposition, and improved visibility), is speculative. These arguments are discussed in the RFG final rule at, for example, 59 FR 7746 and 7751.

C. Cost-effectiveness

API argues that EPA has understated the impact of the Phase II NO_X reduction standard on costs and refiner flexibility. API claims that if more accurate sulfur removal (''desulfurization'') costs were employed, EPA's cost per ton of NO_X removed would increase to over $10,000. Moreover, API argues that EPA's cost effectiveness analysis does not take into account that NO_X reductions in some areas do not contribute to ozone attainment; API claims that if the benefit of NO_X reductions in Chicago, Milwaukee and Houston, which have been granted conditional section 182(f) waivers, is reduced to zero or less, EPA's cost-effectiveness estimate would rise from $5,000 to $7,500 per ton.

API also argues that EPA should have included a more extensive array of stationary source NO_X control measures that compare favorably to EPA's cost-effectiveness estimate, particularly if that estimate is changed in light of API's arguments on desulfurization costs and reduced ozone benefits.

Finally, API argues that major stationary sources offer more potential for overall reduction in air pollution, and that the cost-effectiveness of Phase II NO_X controls is higher than stationary combustion sources with lower potential for overall NO_X reduction. API argues that, unlike mobile source control, major stationary source control can be targeted to avoid the cost of NO_X control where it is not needed and any adverse effect on ozone because of atmospheric chemistry. API's arguments are discussed in the RFG final rule at, for example, 59 FR 7752–7754.

III. Request for Comment

EPA requests comment on all the issues raised in API's petition for reconsideration. EPA is also interested in the potential impact of a delay in implementation or elimination of the Phase II RFG NO_X standard on state implementation plans for attaining compliance with the ozone NAAQS. EPA solicits new information on costs and air quality benefits associated with the Phase II RFG NO_X reduction standard, including non-ozone air quality benefits.

IV. Conclusion

After considering all public comments and any other relevant information available to EPA, the agency will make a decision regarding API's petition for reconsideration.

Dated: June 28, 1996.

Mary D. Nichols,

Assistant Administrator, Office of Air and Radiation.

[FR Doc. 96–17318 Filed 7–8–96; 8:45 am]

BILLING CODE 6560–50–P

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40 CFR Part 300

[FRL–5533–1]

National Oil and Hazardous Substances Contingency Plan; National Priorities List Update

AGENCY: Environmental Protection Agency.

ACTION: Notice of Deletion of the Carter Lee Lumber Company Superfund Site from the National Priorities List (NPL).

SUMMARY: The Environmental Protection Agency (EPA) announces the deletion of the Carter Lee Lumber Company Site in Indiana from the National Priorities List (NPL). The NPL is Appendix B of 40 CFR Part 300 which is the National Oil and Hazardous Substances Contingency Plan (NCP), which EPA promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended. This action is being taken by EPA and the State of Indiana, because it has been determined that Responsible Parties have implemented all appropriate response actions required. Moreover, EPA and the State of Indiana have determined that remedial actions conducted at the site to date remain protective of public health, welfare, and the environment.

EFFECTIVE DATE: July 9, 1996.

FOR FURTHER INFORMATION CONTACT: Deborah Orr at (312) 886–7576 (SR–6J), Remedial Project Manager, Superfund Division, U.S. EPA—Region V, 77 West Jackson Blvd., Chicago, IL 60604. Information on the site is available at the local information repository located at: Hawthorn Community Center, 2440 West Ohio Street, Indianapolis, IN and the offices of the Indiana Department of Environmental management, 100 N. Senate Avenue, N1255, Indianapolis, IN. Requests for comprehensive copies of documents should be directed formally to the Regional Docket Office. The contact for the Regional Docket Office is Jan Pfundheller (H–7J), U.S.

EPA, Region V, 77 W. Jackson Blvd., Chicago, IL 60604, (312) 353–5821.

SUPPLEMENTARY INFORMATION: The site to be deleted from the NPL is Carter Lee Lumber Company Site located in Indianapolis, Indiana. A Notice of Intent to Delete for this site was published May 8, 1996 (61 FR 20785). The closing date for comments on the Notice of Intent to Delete was June 7, 1996. EPA received no comments and therefore no Responsiveness Summary was prepared.

The EPA identifies sites which appear to present a significant risk to public health, welfare, or the environment and it maintains the NPL as the list of those sites. Sites on the NPL may be the subject of Hazardous Substance Response Trust Fund (Fund-) financed remedial actions. Section 300.425(e)(3) of the NCP states that Fund-financed actions may be taken at sites deleted from the NPL in the unlikely event that conditions at the site warrant such action. Deletion of a site from the NPL does not affect responsible party liability or impede agency efforts to recover costs associated with response efforts.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous Waste, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: June 24, 1996.

David A. Ullrich,

Acting Regional Administrator, U.S. EPA, Region V.

40 CFR part 300 is amended as follows:

PART 300—[AMENDED]

1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp.; p.351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp.; p. 193.

Appendix B—[Amended]

2. Table 1 of Appendix B to part 300 is amended by removing the Site ''Carter Lee Lumber Company Site, Indianapolis, Indiana''.

[FR Doc. 96–17322 Filed 7–8–96; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

46 CFR Part 42

[CGD 96–006]

RIN 2115–AF29

Extension of Great Lakes Load Line Certificate

AGENCY: Coast Guard, DOT.

ACTION: Direct final rule.

SUMMARY: By this direct final rule, the Coast Guard is revising the limit on the number of days that a Great Lakes Load Line Certificate extension may be granted from 90 days to 365 days. This action is taken to extend the Great Lakes load line certificate interval from the current 5 years and 90 days maximum interval to a 6-year maximum interval.

DATES: This rule is effective on October 7, 1996, unless the Coast Guard receives written adverse comments or written notice of intent to submit adverse comments on or before September 9, 1996. If such comments or notice are received, the Coast Guard will withdraw this direct final rule, and a timely notice of withdrawal will be published in the Federal Register.

ADDRESSES: Comments may be mailed to the Executive Secretary, Marine Safety Council (G–LRA/3406) (CGD 96–006), U.S. Coast Guard Headquarters, 2100 Second Street SW., Washington, DC 20593–0001, or may be delivered to room 3406 at the same address between 9:30 a.m. and 2 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 267–1477.

The Executive Secretary maintains the public docket for this rulemaking. Comments will become part of this docket and will be available for inspection or copying at room 3406, U.S. Coast Guard Headquarters, between 9:30 a.m. and 2 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LCDR Mark R. DeVries, G–MOC, (202) 267–0009.

SUPPLEMENTARY INFORMATION:

Request for Comments

Any comments must identify the names and address of the person submitting the comment, specify the rulemaking docket (CGD 96–006) and the specific section of this rule to which each comment applies, and give the reason for each specific comment. Please submit two copies of all comments and attachments in an unbound format, no larger than 8+ by 11 inches, suitable for copying and electronic filing. Persons wanting acknowledgment of receipt of comments should enclose stamped, self-addressed postcards or envelopes.

Regulatory Information

The Coast Guard is publishing a direct final rule, the procedures of which are outlined in 33 CFR 1.05–55, because no adverse comments are anticipated. If no adverse comments or any written notice of intent to submit adverse comment are received within the specified comment period, this rule will become effective as stated in the **DATES** section. In that case, approximately 30 days prior to the effective date, the Coast Guard will publish a notice in the Federal Register stating that no adverse comment was received and confirming that this rule will become effective as scheduled. However, if the Coast Guard receives written adverse comment or written notice of intent to submit adverse comment, the Coast Guard will publish a notice in the final rule section of the Federal Register to announce withdrawal of all or part of this direct final rule. If adverse comments apply to only part of this rule, and it is possible to remove that part without defeating the purpose of this rule, the Coast Guard may adopt as final those parts of this rule on which no adverse comments were received. The part of this rule that was the subject of adverse comment will be withdrawn. If the Coast Guard decides to proceed with a rulemaking following receipt of adverse comments, a separate notice of proposed rulemaking (NPRM) will be published and a new opportunity for comment provided.

A comment is considered ''adverse'' if the comment explains why this rule would be inappropriate, including a challenge to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change.

Background and Purpose

Before 1973, the load line intervals for vessels operating on the Great Lakes was 6 years in length. In 1973, the load line regulations were revised and the 6-year interval was reduced to 5 years with a provision to allow for a 90-day extension. The reduction in the interval was because of the higher frequency and shorter length of Great Lakes voyages, the presumed safety risks resulting from the increased amount of dockings, and the Great Lakes climatic conditions.

This assumption has proven to be incorrect. The Lake Carriers' Association, whose membership includes the operators of 59 U.S.-Flag freightships on the Great Lakes, has

been able to provide 20 years of data to dispute the additional risk assumption. The Coast Guard agrees that the data does not support the presumption of higher safety risks.

Instead, the reduction in the Great Lakes load line certificate interval caused an unnecessary increased financial burden on the industry without the benefit of an increase in the level of safety. It created this increase in costs by causing more frequent drydockings and reducing the number of days available to carry cargo. This rule will avoid unnecessary costs to the industry by providing for extensions of Great Lakes load line certificate intervals up to 365 days for qualifying Great Lakes vessels.

Discussion of Rules

This rule revises 46 CFR Part 42 by changing the limit on the number of days that a Great Lakes load line certificate may be extended from 90 days to 365 days. This expands the Great Lakes load line certificate interval to a maximum interval of 6 years, including allowable extensions.

Regualtory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has not been reviewed by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. This rule impacts only vessel owners and operators in possession of a Great Lakes Load Line Certificate, and will result in cost savings to vessels receiving an extension of this certificate by allowing vessel owners and operators greater flexibility in the coordination and scheduling of required examinations.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider the economic impact on small entities of a rule for which a general notice of proposed rulemaking is required. ''Small entities'' may include (1) Small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields and (2) governmental jurisdictions with populations of less than 50,000.

This rule will create cost savings for vessel owners and operators in possession of a great Lakes load line certificate without additional costs to other small entities. Therefore, the Coast Guard finds that this rule will not have a significant economic impact on a substantial number of small entities. Any comments submitted in response to this finding will be evaluated under the criteria described earlier in the preamble for comments.

Collection of Information

This rule contains no collection-of-information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this rule under the principles and criteria contained in Executive Order 12612 and has determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that, under paragraph 2.B.2 of Commandant Instruction M16475.1B, as revised by 59 FR 38654, July 29, 1994, this rule is categorically excluded from further environmental documentation. Section 2.B.2.e(34)(d) of that instruction excludes ''regulations concerning manning, documentation, admeasurement, inspection, and equipping of vessels.'' A ''Categorical Exclusion Determination'' is available in the docket for inspection or copying where indicated under **ADDRESSES.**

List of Subjects in 46 CFR Part 42

Penalties, Reporting and record keeping requirements, Vessels.

For the reasons set out in the preamble, the Coast Guard amends 46 CFR part 42 as follows:

PART 42—DOMESTIC AND FOREIGN VOYAGES BY SEA

1. The authority citation for part 42 continues to read as follows:

Authority: 46 U.S.C. 2103; 49 CFR 1.45, 1.46; section 42.01–5 also issued under the authority of 44 U.S.C. 3507.

2. In § 42.07–45, paragraph (d)(2) introductory text is revised to read as follows:

§ 42.07–45 Loan line certificates.

* * * * *

(d) * * *

(2) A Great Lakes certificate is issued for 5 years and may be extended by the Commander, Ninth Coast Guard District, up to 365 days from date of the—

* * * * *

Dated: July 2, 1996.

J.C. Card,

Rear Admiral, U.S. Coast Guard, Chief, Marine Safety and Environmental Protection.

[FR Doc. 96–17461 Filed 7–8–96; 8:45 am]

BILLING CODE 4910–14–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Chapter I

[CC Docket No. 96–21, FCC 96–288]

Bell Operating Company Provision of Out-of-Region Interstate, Interexchange Services

AGENCY: Federal Communications Commission.

ACTION: Interim rule.

SUMMARY: In this *Report and Order,* the Commission facilitates the efficient and rapid provision of out-of-region, domestic, interstate, interexchange services by the BOCs, as contemplated by the Telecommunications Act of 1996 (1996 Act), while still protecting ratepayers and competition in the interexchange market, by removing dominant regulation for BOCs that provide such services through an affiliate that complies with certain safeguards. These safeguards are the same as those that have applied for more than ten years to affiliates of independent local exchange companies (LECs) (*i.e.,* exchange telephone companies, including GTE, other than the BOCs) that are regulated as non-dominant interexchange carriers under the rules established in the *Competitive Carrier* proceeding. These rules will permit the rapid entry by the BOCs into the provision of out-of-region interstate, interexchange services while providing protection against anticompetitive conduct.

EFFECTIVE DATE: August 8, 1996.

FOR FURTHER INFORMATION CONTACT: Michael Pryor (202) 418–0495 or Melissa Waksman (202) 418–0913, Common Carrier Bureau, Policy and Program Planning Division.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order* adopted on June 28, 1996, and released on July 1, 1996, FCC 96–288. The full text of this Report and Order is available for inspection and copying during normal business hours in the FCC Reference Center (Room

239), 1919 M St., N.W., Washington, DC. The complete text also may be purchased from the Commission's copy contractor, International Transcription Service, Inc., (202) 857–3800, 2100 M St., NW., Suite 140, Washington, DC 20037.

Paperwork Reduction: Public burden for this recordkeeping requirement is estimated to average 6056 hours per response, including the 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 this burden estimate or any other aspect of this recordkeeping requirement, including suggestions for reducing the burden, to the Federal Communications Commission, Records Management Branch, Paperwork Reduction Project, Washington, D.C. 20554 and to the Office of Management and Budget, Paperwork Reduction Project, Washington, D.C. 20503.

Synopsis of Notice of Proposed Rulemaking

I. Introduction

1. In enacting the Telecommunications Act of 1996 (1996 Act), Pub. L. No. 104–104, 110 Stat. 56 (1996) *codified at* 47 U.S.C. §§ 151 *et seq,* Congress sought to establish ''a pro-competitive, de-regulatory national policy framework'' for the United States telecommunications industry. The 1996 Act, among other things, provided that upon enactment the Bell Operating Companies (BOCs) could provide interLATA telecommunications services originating outside of their in-region states. In response to the new legislation, the Commission released, on February 14, 1996, a Notice of Proposed Rulemaking, 61 FR 6607 (Feb. 21, 1996), in which the Commission proposed an interim regime to govern the BOCs' provision of out-of-region domestic, interstate, interexchange service. The Notice addressed all ''out-of-region'' interstate, interexchange services (including interLATA and intraLATA services). Eighteen parties filed comments and thirteen parties filed reply comments.

2. Under our existing rules, BOC provision of out-of-region, interstate, interexchange services is subject to dominant carrier regulation. In order to facilitate the efficient and rapid provision of out-of-region, domestic, interstate, interexchange services by the BOCs, as contemplated by the 1996 Act, while still protecting ratepayers and competition in the interexchange market, we remove dominant regulation for BOCs that provide out-of-region, interstate, interexchange services through an affiliate that complies with certain safeguards. These safeguards are the same as those that have applied for more than ten years to affiliates of independent local exchange companies (LECs) that are regulated as non-dominant interexchange carriers under the rules established in the *Competitive Carrier* proceeding. The safeguards require that the affiliate: (1) maintain separate books of account from the LEC; (2) not jointly own transmission or switching facilities with the LEC; and (3) take any tariffed services from the affiliated LEC pursuant to the terms and conditions of the LEC's generally applicable tariff. We also conclude that a BOC affiliate providing out-of-region, domestic, interstate, interexchange services should be treated, for purposes of the BOCs' accounting, as a nonregulated affiliate under the Commission's joint cost and affiliate transactions rules, just as independent LEC affiliates are now treated.

3. The regime adopted in this Report and Order is expressly designed as an interim measure to facilitate the BOCs' prompt provision of out-of-region, domestic, interstate, interexchange services. In March 1996, the Commission sought comment in the *Interexchange NPRM,* on whether to modify or eliminate these affiliate requirements as a condition for non-dominant treatment of independent LEC provision of out-of-region, interstate, interexchange services. We also sought comment on whether, if we modify or eliminate these requirements for independent LECs, we should also eliminate or modify our treatment of BOC out-of-region, interstate, interexchange services. We will establish final rules for BOC out-of-region, interstate, interexchange services in that proceeding.

II. Background

A. The Competitive Carrier Proceeding

4. Between 1979 and 1985, the Commission conducted the *Competitive Carrier* proceeding, in which it examined how its regulations should be adapted to reflect and facilitate the increasing competition in telecommunications markets. In a series of orders, the Commission distinguished between carriers with market power (dominant carriers) and those without market power (non-dominant carriers). The Commission gradually relaxed its regulation of non-dominant carriers because it concluded that non-dominant carriers lacked the incentive and ability to engage in conduct that might be anticompetitive or otherwise inconsistent with the public interest.

5. In its *First Report and Order,* 45 FR 52453, November 18, 1980, the Commission classified AT&T and its then-affiliated local exchange companies as well as independent local exchange companies as dominant carriers and concluded that these dominant carriers should be subject to the ''full panoply'' of Title II regulation. Recently, in light of increasing competition in the interstate, domestic, interexchange telecommunications market, and evidence that AT&T no longer possesses the ability to control prices unilaterally, the Commission reclassified AT&T as a non-dominant carrier in that market.

6. In its *Fourth Report and Order,* 48 FR 52452, November 1983, the Commission considered how it should regulate the provision of interstate, interexchange services by independent LECs. Because the Modification of Final Judgment, *United States* v. *Western Elec. Co.,* 552 F. Supp. 131 (D.D.C. 1982), *aff'd. sub nom., Maryland* v. *United States,* 460 U.S. 1001 (1983), prohibited BOCs from offering interLATA services, the *Fourth Report and Order* addressed only the interstate, interexchange offerings of independent LECs. The Commission determined that interexchange carriers affiliated with independent LECs would be regulated as non-dominant carriers. In the *Fifth Report and Order,* 49 FR 34824, September 4, 1984, the Commission explained its definition of the term ''affiliate'' as ''a carrier that is owned (in whole or in part) or controlled by, or under common ownership (in whole or in part) or control with, an exchange telephone company,'' and identified three separation requirements that the affiliate must meet in order to qualify for non-dominant treatment. These requirements are that the affiliate: (1) maintain separate books of account; (2) not jointly own transmission or switching facilities with the LEC; and (3) if it uses the LEC's services, it should acquire them via the LEC's tariffs. The Commission further concluded that, if the LEC provided interstate, interexchange services directly, rather than through an affiliate, those services would be subject to dominant carrier regulation.

7. The *Fifth Report and Order* also addressed the regulation of the BOCs' provision of interLATA services:

> The BOCs currently are barred by the [Modification of Final Judgment] from providing interLATA services. . . . If this bar is lifted in the future, we would regulate the BOCs' interstate, interLATA services as dominant until we determined what degree

of separation, if any, would be necessary for the BOCs or their affiliates to qualify for nondominant regulation.

B. The 1996 Act and the BOC Out-of-Region Notice of Proposed Rulemaking

10. Section 271(b)(2), added by the 1996 Act, provides:

> A Bell operating company, or any affiliate of that Bell operating company, may provide interLATA services originating outside its in-region States after the date of enactment of the Telecommunications Act of 1996, subject to subsection (j).

Thus, the 1996 Act does not require a BOC to obtain Commission authorization prior to offering out-of-region, interstate, interLATA services. The 1996 Act, however, does not modify the Commission's determination in the *Fifth Report and Order* that BOC provision of interstate, interLATA services initially would be subject to dominant carrier regulation.

11. Immediately after the 1996 Act became law, we issued the *BOC Out-of-Region NPRM,* in which we proposed, under certain conditions, to remove dominant carrier regulation of the BOCs' provision of out-of-region, interstate, interexchange services. In our Notice, we tentatively concluded that, as an interim measure, if a BOC creates an affiliate to provide out-of-region, interstate, interexchange services (including interLATA and intraLATA services), and if the affiliate satisfies the minimal separation requirements set forth in the *Fifth Report and Order* that apply to the interexchange affiliates of independent LECs, then the BOC affiliate's provision of those interexchange services would be regulated on a non-dominant basis. We also noted that LECs providing interexchange services through affiliates pursuant to the *Fifth Report and Order* treat those affiliates as nonregulated affiliates under the Commission's joint cost rules and affiliate transactions rules for exchange carrier accounting purposes. In our Notice, we sought comment on whether a BOC affiliate providing out-of-region, interstate, interexchange services also should be treated as a nonregulated affiliate for BOC accounting purposes. Finally, we tentatively concluded that, at least for now, if a BOC provides out-of-region, interstate, interexchange services directly, or through an affiliate that fails to comply with these minimal separation requirements, then dominant carrier regulation would be retained for those services.

III. Discussion

A. The Purpose of the Interim Rules

12. This proceeding is necessary to enable the BOCs to begin competing in an out-of-region area in the interexchange market on a non-dominant basis. Currently, BOC provision of interstate, interexchange service is subject to dominant carrier regulation until we determine the degree of separation, if any, necessary for non-dominant treatment. Thus, BOC out-of-region services would be subject to dominant regulation, whether those services were offered directly by the BOC or through another entity, no matter how structurally separate from the BOC. We take no position in this proceeding on whether the structural separation requirements, other safeguards established by the 1996 Act, and our existing regulations that would apply to BOC provision of in-region services are sufficient to allow us to relax dominant carrier regulation for the separate subsidiaries through which the BOCs must provide in-region, interLATA services. *See* 47 U.S.C. § 272. We will address that issue in a separate proceeding.

13. In our Notice, we tentatively concluded that we could remove dominant carrier regulation of BOC out-of-region, interstate, interexchange services by applying to the BOCs the same rules that have worked well for independent LECs. These rules were specifically designed to impose minimal burdens on the smaller, independent LECs, and thus are less stringent than the structural separation required under our *Computer II* regime, and contain fewer restrictions than imposed by the 1996 Act for BOC provision of in-region, interLATA services. At the same time, the Commission found in the *Fifth Report and Order* that these separation requirements provided some protection against anticompetitive abuses that could arise from the LECs' control over local bottleneck facilities.

14. Because we believe that we should move expeditiously in order to advance the goals of the 1996 Act, we specifically stated in the Notice that the actions we take in this proceeding would be interim. By applying the well-established rules applicable to independent LECs as an interim measure, we are able to: remove dominant carrier regulation for BOC out-of-region, interstate, interexchange services, thereby facilitating prompt and competitive entry by the BOCs into those services; have the same level of assurance of protecting competition and ratepayers as we have with independent LECs and their interexchange affiliates; and avoid engaging in a protracted proceeding. We have already issued a Notice in which we initiate a more comprehensive review of the rules that are applicable to both independent LECs and the BOCs in the provision of out-of-region, interstate, interexchange services. In the *Interexchange NPRM,* we sought comment on whether it may be appropriate to modify or eliminate the minimal separation requirements applied to independent LEC affiliates providing interstate, interexchange services originating outside of their local exchange areas. We also sought comment on whether, if we do modify or eliminate such requirements for independent LECs, we should apply the same requirements to BOC provision of out-of-region, interstate, interexchange services. We will finalize our rules governing both BOC and independent LEC provision of out-of-region, interstate, interexchange services in that proceeding.

B. Non-dominant Classification for BOC Affiliates

15. The record does not dissuade us from proceeding on an interim basis as proposed in the Notice. NYNEX and Pactel support, as an interim measure, adoption of the *BOC Out-of-Region NPRM's* tentative conclusions, including use of the Commission's joint cost and affiliate transactions rules. NYNEX contends that the proposed rules are ''an excellent first regulatory step that the Commission can take promptly to enable BOC entry into the long distance service markets.'' Pactel supports the rules as a method of ensuring regulatory parity among all exchange companies, BOCs and independent LECs, even though Pactel disputes that the BOCs have market power in the interexchange market.

16. The remaining BOCs object to removing dominant regulation only for affiliates meeting the *Fifth Report and Order* requirements and contend that out-of-region, interstate, interexchange services should be regulated as non-dominant even if provided on an unseparated basis. These commenters raise essentially three arguments: (1) BOCs do not have market power in the interexchange market under the criteria, such as market share, established in the *Competitive Carrier* proceeding and those applied in reclassifying AT&T as a non-dominant interexchange carrier; (2) BOCs have neither the ability nor the incentive to leverage their control over local facilities to impede competition in the interexchange market, especially given current regulations and the provisions of the 1996 Act that are designed to open the local market to

competition; and (3) the proposed separation requirements for out-of-region interexchange services are inconsistent with the 1996 Act.

17. BellSouth additionally argues that, by proposing to regulate BOCs as dominant if they directly provide out-of-region, interexchange services based on their market power in the provision of local services, we are resurrecting the ''all services'' approach. BellSouth states that, in the *Competitive Carrier* orders, the Commission adopted an ''all services'' approach under which a finding that a carrier was dominant in the provision of one service subjected a carrier to dominant regulation of all services. BellSouth argues that, under this ''all services'' approach, the Commission ruled that bottleneck facilities were prima facie evidence of dominance in all markets. BellSouth maintains that the Commission rejected this approach in the *AT&T Reclassification Order.* We reject this analysis. The ''all services'' question addressed in the *AT&T Reclassification Order* was whether the Commission could find AT&T non-dominant only if ''AT&T lacks the ability to control the price of every tariffed service *in the relevant market.*'' A very different question is posed by the BOCs entry into out-of-region, interstate, interexchange services: whether a firm with market power in one relevant market (the local exchange and exchange access market) can leverage that power to gain market power or an unfair advantage in another, related market (the interexchange market).

18. As for the non-BOC commenters, MCI and TRA argue that, given the potential for the BOCs to engage in anticompetitive conduct, the BOC affiliate should be regulated as dominant. Almost all of the other non-BOC commenters support non-dominant regulation of BOC out-of-region services if provided through a separate affiliate, but contend that the safeguards proposed in the Notice are insufficient to protect against abuses by the BOCs. Specifically, these parties claim that without these additional safeguards the BOCs could use their control over local exchange facilities to unfairly discriminate in pricing or service quality against competing interexchange carriers or could cross-subsidize their long distance operations by shifting costs to the local exchange and exchange access operations. They urge the Commission, therefore, to impose full structural separation on the out-of-region affiliate, including the separations imposed by section 272 on the in-region interexchange affiliate. They also seek to bar joint marketing of local and out-of-region services or, at least, require that marketing personnel and operations be separated. Some ask the Commission to require that the BOC provide all Title II services to its affiliate at the generally applicable tariffed rates and that all non-Title II services and access to information obtained by the BOC by virtue of its provision of local exchange service be provided on a non-discriminatory basis or that such information not be shared at all. Finally, non-BOC commenters dispute claims that the Notice's proposals are inconsistent with the 1996 Act.

19. We adopt here the interim rules proposed in the Notice, at least until completion of our broader rulemaking proceeding, the *Interexchange NPRM.* The *Fifth Report and Order* safeguards we adopt herein on an interim basis have worked relatively well since 1984 to protect against potential abuses by the independent LECs in their provision of interexchange services and we believe that they will provide adequate interim protection as the BOCs begin providing out-of-region interexchange services. As the Commission noted in the *Fifth Report and Order,* these safeguards provide some protection against ''cost-shifting and anticompetitive conduct.'' These safeguards have been applied to independent LEC provision of interexchange services originating in and out of their regions and should provide sufficient interim safeguards for BOC provision of solely out-of-region services. Additionally, these safeguards will be supplemented with the application of our cost allocation and affiliate transaction rules, as explained below, which provide further protection against cost misallocations. Moreover, no party has presented persuasive evidence to show that, at this time, these rules will not be effective interim measures.

20. At the same time, we believe that these minimal requirements should be in place pending further analysis of these issues. Not only has the Commission adopted an NPRM to address these specific issues, but we also have launched various proceedings, and are in the process of issuing further rulemakings, relating to the implementation of various aspects of the 1996 Act. These proceedings touch upon issues raised in this proceeding, such as the proper market definition and the scope of various safeguards. We believe it is prudent to assess the record in those proceedings in order to assist us in adopting a comprehensive and cohesive framework that addresses the myriad issues involving BOC provision of services that the BOCs previously have been barred from offering.

21. Thus we reject AT&T's argument that the proposed rules should not be adopted because, AT&T contends, they improperly depart from the use of a single, nationwide, interexchange market without submarkets without providing a reasoned explanation. The Notice proposed to apply, on an interim basis, the same rules to BOC out-of-region services that we apply to independent LECs. We do not find that AT&T has presented persuasive reasons to depart from this prior precedent for purposes of these interim rules. Moreover, in the Notice, we explicitly proposed to address only BOC provision of out-of-region, interstate, interexchange services. At the same time, we made clear that we were planning to adopt these rules on an interim basis, pending a future proceeding to consider more fully the long-term issues raised by BOC entry into out-of-region, interstate, interexchange services. We note that on March 25, 1996, we released the *Interexchange NPRM* initiating that proceeding. In proposing to look only at BOC provision of out-of-region, interstate, interexchange service here, we sought to balance the goal of the 1996 Act to allow swift BOC entry into the interexchange market, subject to interim safeguards, with the need for a comprehensive review of our rules. We believe it is within our discretion to conduct our proceedings in such a manner as to accommodate these twin purposes.

22. We find that our interim plan of removing dominant carrier regulation for BOC affiliates meeting the *Fifth Report and Order* separation requirements and retaining dominant regulation for BOCs that provide out-of-region services directly will not impose an unreasonable burden on the BOCs. Initially, we believe it is important to clarify the scope of the *Fifth Report and Order* separation requirements. Most commenters refer to the *Fifth Report and Order* requirements as structural separation. This is true only in the sense that the BOC or LEC non-dominant interexchange affiliate is a separate legal entity. In no other sense do we require ''structural separation.'' Indeed, in the *Fifth Report and Order,* the Commission specifically rejected arguments that structural separation requirements should be imposed between an independent LEC and its interexchange affiliate because the Commission found that structural separation would impose unreasonable burdens on smaller, independent LECs. The Commission specifically sought to avoid imposing

excessive burdens and noted that the LEC affiliate qualifying for non-dominant treatment ''is not necessarily structurally separated from the exchange telephone company in the sense ordered in the *Second Computer Inquiry* * * * (*e.g.*, fully-separated personnel and marketing are not necessary for nondominant treatment).'' Thus, except for the ban on joint ownership of transmission and switching facilities, a restriction which we believe should pose little, if any, burden on the provision of out-of-region, interstate, interexchange services, the BOC and the interexchange affiliate will be able to share personnel and other resources or assets. The affiliate may be staffed by BOC personnel, housed in existing BOC offices, and use BOC marketing or other services. Providing interexchange services through such an affiliate will not impede the BOCs' ability to realize efficiencies gained through the use of joint resources. To help ensure that the BOCs properly allocate the costs of any services provided to the interexchange affiliate, however, we require that the BOC treat this affiliate for accounting purposes as a nonregulated affiliate and therefore subject to our cost allocation and affiliate transactions rules.

23. Additionally, we clarify the separate books of account requirement and the requirement that to the extent the affiliate obtains BOC services it do so under the terms of the BOC's tariff. We do not require that the interexchange affiliate maintain separate books of account that comply with our Part 32 rules. Instead, the separate books of account requirement refers to the fact that, as a separate legal entity, the affiliate must maintain its own books of account as a matter of course. This is consistent with the current accounting treatment of the interexchange affiliates of independent LECs. Books of account refer to the financial accounting system a company uses to record, in monetary terms, the basic transactions of a company. These books of account reflect the company's assets, liabilities, and equity, and the revenues and expenses from operations. Each company has its own separate books of account. The Commission's Part 32 rules, the Uniform System of Accounts (USOA), prescribe the books of account for the telephone companies. The Part 32 USOA, however, is not required to be kept by affiliates of a telephone company. These affiliates maintain their own separate books of account. We note that, if a telephone company decides to conduct out-of-region, interstate, interexchange service within the telephone company without using a separate affiliate, this activity would be reflected in the telephone company's USOA accounts, because the USOA reflects the telephone company's total operations. As to the tariff requirement, we clarify that this provision applies only to services for which the BOC is required to file a tariff, not to detariffed services such as billing and collection. The provision also only applies when the affiliate obtains tariffed services from its affiliated BOC.

24. Parties have offered no credible evidence to support contentions that the *Fifth Report and Order* separation requirements constitute burdensome regulation. Indeed, the entry of interexchange carriers affiliated with independent LECs over the past decade serves as evidence that these conditions will not prevent the BOCs from competing effectively. Moreover, we note that several BOCs have already established, or plan to establish, subsidiaries through which they will provide interexchange services that meet or exceed these separation requirements. We believe that separation requirements designed to accommodate the resources of small independent LECs will not impose an unreasonable burden on the much larger regional Bell companies, particularly on an interim basis.

25. Finally, we conclude, as an interim measure, that if a BOC chooses to offer out-of-region interstate interexchange services directly, it will be subject to dominant carrier regulation and to price cap regulation. Specifically, we require that the BOCs include such services in the price cap Basket for interexchange services. *See* 47 CFR § 61.42(d)(4).

C. Consistency With the 1996 Act

26. Several BOC commenters argue that the separate affiliate requirement, even as an interim measure, is inconsistent with the provisions of the 1996 Act. They contend that the 1996 Act specifically excluded out-of-region services from the separate affiliate requirement contained in new section 272. Some further argue that, because dominant regulation is so onerous, conditioning non-dominant treatment on complying with the separation requirements effectively requires BOCs to establish a separate affiliate to provide out-of-region interstate, interexchange services in contravention of the 1996 Act. They also argue, more generally, that the proposed rules are inconsistent with the overall deregulatory emphasis of the new legislation.

27. Bell Atlantic contends that the proposed separation requirements are inconsistent with the 1996 Act for two reasons: (1) section 272(f) contains a sunset provision for the in-region affiliate whereas the proposed separation requirements are open-ended; and (2) a BOC interexchange affiliate providing out-of-region services would be barred from jointly owning transmission and switching facilities with its operating company affiliate, whereas Section 272 contains no such restriction for the in-region separate affiliate. Bell Atlantic concludes that it would have to establish two subsidiaries, one for in-region and one for out-of-region services.

28. Non-BOC commenters dispute these arguments. Some argue that, because the 1996 Act is silent as to the type of regulatory regime that the Commission should impose on the BOCs' provision of out-of-region interexchange services, the statute contemplates that the Commission may apply its existing dominant/nondominant regulatory regime. These parties further point out that the separate subsidiary provisions of the 1996 Act contain a savings clause which states that ''[n]othing in this subsection shall be construed to limit the authority of the Commission under any other section of this Act to prescribe safeguards consistent with the public interest, convenience and necessity.'' Vanguard contends that the BOCs are essentially arguing that the 1996 Act repealed the Commission's existing statutory authority to apply its dominant carrier rules to BOC interexchange affiliates by implication. Vanguard asserts that a statutory construction that would repeal an agency's authority by implication is ''highly disfavored'' by the courts except where there is an irreconcilable conflict between the two statutes or where there is compelling evidence that Congress intended to repeal the prior statute. Sprint and others contend that the proposed safeguards are less burdensome than the statutory separate subsidiary requirement and note that, while the 1996 Act mandates a separate subsidiary to provide in-region services, the Commission's proposal permits the BOCs to offer out-of-region services through an affiliate or directly.

29. We reject the contention that section 272(a)(2) prohibits us from retaining the dominant/non-dominant regulatory framework which the Commission has applied to interexchange carriers prior to passage of the 1996 Act for BOC provision of out-of-region, interstate, interexchange services. More specifically, we do not

agree that, by excluding out-of-region services from those services that a BOC must provide through a structurally separate affiliate, section 272(a)(2) bars the Commission from according non-dominant regulation of BOC out-of-region, interstate, interexchange services only to BOC affiliates that comply with the separation requirements we adopt in this Order. Section 272(a)(2), relied upon by the BOC commenters, provides in pertinent part that:

> The services for which a separate affiliate is required by paragraph (1) are:
> * * * * *
> (B) Origination of interLATA telecommunications services, other than—
> * * * * *
> (ii) out-of-region services described in section 271(b)(2).

As noted by MCI, the legislation is silent on the issue of dominant/non-dominant regulation of BOC interLATA services. We conclude that Congress did not intend by implication to repeal our authority to impose dominant or non-dominant regulatory treatment as we deem necessary to protect the public interest consistent with our statutory mandates. To the contrary, Section 601(c) of the 1996 Act provides that we are not to presume that Congress intended to supersede our existing regulations unless expressly so provided.

30. Nor is there any inconsistency between the separation requirements we adopt by this Order as an interim measure and the 1996 Act. We do not mandate that the BOCs provide out-of-region, interstate, interexchange services through a separate affiliate. Instead, this Order concludes that, on an interim basis, BOCs will continue to be subject to dominant carrier treatment if they offer out-of-region interstate, interexchange services directly. The same requirement has applied to all independent LECs since 1984. This order, in effect, offers the BOCs a choice of providing out-of-region, interstate, interexchange services under dominant regulation if they wish to furnish those services directly or under non-dominant regulation if they wish to offer those services through a separate affiliate that meets the separation requirements.

31. We also note that the 1996 Act's provisions for the structurally separate in-region subsidiary contain more restrictions than those that will apply to the BOC affiliates' provision of out-of-region, interstate, interexchange services as a non-dominant carrier. For example, the 1996 Act requires that the separate subsidiary that must be established to provide in-region interLATA services must have separate officers, directors, and employees, and may not obtain credit under any arrangement that would permit recourse to the BOC. *See* 47 U.S.C. § 272(b). None of these requirements applies to the BOCs' out-of-region affiliate.

32. Bell Atlantic contends, however, that our proposed separation conditions are, in fact, more rigorous than those established by the 1996 Act for in-region services because we have not suggested a sunset date and have barred joint ownership of transmission and switching facilities. We are seeking comment in the *Interexchange NPRM* on whether to modify or eliminate the separation requirements for independent LECs in their provision of out-of-region, interstate, interexchange service as a condition for non-dominant treatment. We are also seeking comments on whether, if we modify or eliminate these separation requirements for independent LECs, we should apply the same treatment to BOC provision of out-of-region, interstate, interexchange service. Bell Atlantic's argument is more appropriately addressed in that proceeding. During the interim period that will be covered by the rules we promulgate today, a prohibition on joint ownership of switching and transmission facilities should cause no hardship on the BOC provision of out-of-region services because, as the BOCs maintain, they initially will be using other carriers' facilities and because of the geographic separation of in-region facilities and out-of-region services. Additionally, the fact that the 1996 Act contains a sunset provision for certain restrictions is not a basis for concluding that our interim rules for BOC out-of-region, interstate, interexchange services are inconsistent with the 1996 Act.

D. Proposed Mergers

33. After the record in this proceeding closed, SBC Communications Inc., and Pacific Telesis Group announced, on April 1, 1996, an agreement to merge their operations. Three weeks later, on April 21, 1996, Bell Atlantic and NYNEX announced that they had reached an agreement to merge. We believe that mergers such as these raise concerns with respect to the provision of out-of-region services during the pendency of the merger. Specifically, they raise the concern that, in the period prior to a merger's consummation, one partner to the merger may act in ways to favor those out-of-region services of its merger partner that originate in the first partner's service territory. For example, BOC A may favor BOC B's long distance services originating in BOC A's territory because BOC A may eventually share in BOC B's profits. We do not believe that the record in this proceeding provides an adequate basis on which to address the specific concerns raised by such pending mergers. Accordingly, we exclude from the services covered by this Order, those out-of-region services that originate in the in-region states of a merger partner during the period prior to the consummation of the merger. Given the interim nature of the rules we are establishing in this Order, and the fact that we are not aware of plans by any of the potential merger partners to provide out-of-region services originating in their respective partners' service territories, we believe that this approach likely will not impose any burdens on the affected parties. Should such parties determine, however, to provide such services, those parties should request the Commission, on an individual case basis, for a determination of whether such services can be provided on a non-dominant basis. Because our concern relates to the incentives of one party to favor the operations of the other party during the pendency of the merger, should an announced merger not be consummated, the interim rules established in this Order for out-of-region services shall apply to all out-of-region services provided by the parties to the proposed merger.

34. Nothing in this section on proposed mergers should be construed as indicating the Commission's position with respect to mergers in other sectors of the telecommunications industry or outside of this particular and unusual context. A unique confluence of circumstances lead us to conclude that it is both reasonable and prudent to postpone our determination of the appropriate regulatory treatment for BOC out-of-region services originating in a potential merger partner's territory. These unique circumstances include: (1) The announcement of mergers, following the closure of the record in this proceeding, involving four of the seven regional Bell companies that would be subject to the rules established in this proceeding; (2) the concern that a BOC, through its position in the local telephone exchange market and its bottleneck control over inputs into the interexchange market, may have the ability, along with the incentive, to favor the out-of-region interexchange services operations of a potential merger partner; (3) the interim nature of these rules; and (4) the 1996 Act's authorization for BOCs to begin providing out-of-region services upon enactment. Given these unique circumstances, we emphasize that this

action is limited to the facts and circumstances set forth in this discussion of proposed mergers.

E. Joint Cost and Affiliate Transactions Rules

35. In the *BOC Out-of-Region NPRM,* we stated that independent LECs providing interexchange services through affiliates pursuant to the *Fifth Report and Order* treat those affiliates as nonregulated affiliates under the Commission's joint cost and affiliate transactions rules for exchange carrier accounting purposes. The *BOC Out-of-Region NPRM* sought comment on whether BOC out-of-region, interstate, interexchange services should be treated as nonregulated services for BOC accounting purposes.

36. AT&T, Pactel, NYNEX, Comptel and Vanguard support the treatment of BOC out-of-region affiliates as non-regulated for accounting purposes. AT&T and Comptel believe such rules are necessary to constrain the BOCs' ability to cross-subsidize and to ensure that local monopoly assets are not used unfairly to advantage long distance operations. Vanguard asserts that the rules would not impose a burden because BOCs account for certain services on this basis already and because such treatment would merely entail setting up the initial account for service, not changing existing procedures. NYNEX states that these rules have been effective as applied to independent LECs, and thus would not be unreasonable to apply to BOCs providing similar services. AT&T and Comptel also contend that some type of independent audit should be performed periodically to certify that long distance affiliates retain their financial independence. Pactel supports application of the affiliate transaction rules as an interim measure.

37. Ameritech opposes application of the affiliate transactions rules to BOC interexchange affiliates. It contends that the joint cost and affiliate transactions rules are designed to allocate costs between regulated and nonregulated activities, not between two regulated services and that, in any event, application of those rules would be unnecessary because the Part 69 rules already require BOCs to identify separately interexchange costs. At a minimum, Ameritech argues that the rules should not apply to any BOC subject to pure price cap regulation at the state and federal level. The Public Utilities Commission of Ohio (PUCO) also opposes treating the affiliate as nonregulated because they contend that accounting abuses are better detected by treating the affiliate's services as regulated.

38. Our existing accounting safeguards for affiliate transactions were developed in the *Joint Cost Order* and are codified in Parts 32 and 64 of our Rules. The Part 64 cost allocation rules prescribe how carriers separate the costs of regulated activities from the costs of nonregulated activities, where the nonregulated activities are performed directly by the carrier rather than through an affiliate. The Part 32 affiliate transactions rules prescribe the way costs are recorded, for Title II accounting purposes, when a regulated carrier does business with its nonregulated affiliates. These rules are designed to prevent local exchange carriers from imposing the costs and risks of their competitive ventures on local telephone ratepayers. These rules do not require carriers or their affiliates to charge any particular prices for assets transferred or services provided; rather, they require carriers to use certain specified valuation methods in determining the amounts to record in their Part 32 accounts, regardless of the prices charged.

39. Because the cost allocation and affiliate transactions rules are an important component of our accounting safeguards, we find that these rules should apply to BOCs providing out-of-region, interstate, interexchange services through a separate affiliate. Even though interLATA services are regulated services under Title II, under the rules we adopt herein, the BOCs, for accounting purposes, will treat the services as nonregulated, so as to make applicable our cost allocation and affiliate transaction rules. The fact that interLATA services are regulated services in and of itself does not eliminate the potential for cost misallocation between the BOCs competitive (interLATA) and noncompetitive (local exchange and exchange access) services. Thus, we believe that application of our cost allocation and affiliate transaction rules is necessary to minimize the possibility that a BOC could improperly shift the costs of its interstate, interexchange operations to its regulated local exchange and exchange access ratepayers. We also note that this requirement is consistent with the current practice of independent LECs that treat their affiliates providing interexchange services as nonregulated for exchange carrier accounting purposes.

40. We find that requiring BOCs to treat affiliates providing out-of-region services as nonregulated will not be unduly burdensome. BOCs currently have systems in place to account for transactions between their nonregulated affiliates (*i.e.,* for transactions between a BOC and any of its information services which are not regulated under Title II). Such a requirement will not entail extensive modification of existing company procedures for the provision of interexchange services because, prior to the passage of the 1996 Act, BOCs were prohibited from providing interstate, interexchange services.

IV. Additional Issues

A. Regulation of CMRS-Related InterLATA Services

41. The *BOC Out-of-Region NPRM* stated that ''BOC provision to commercial mobile radio service customers, of interstate, interLATA services originating outside any of the BOC's in-region states, is included in the out-of-region services addressed in this proceeding.''

42. BellSouth argues that the language in the *Notice* is susceptible to two interpretations. According to BellSouth, it may apply to: (1) The sale of out-of-region, interexchange service by a BOC to unaffiliated commercial mobile radio service (CMRS) customers; or (2) the provision of out-of-region, interexchange CMRS service by a BOC. BellSouth believes that the Commission intended the first of these interpretations—BOCs offering out-of-region long distance to unaffiliated CMRS customers on a stand alone basis, not in conjunction with the BOC's provision of CMRS—and BellSouth opposes applying the Notice's proposed rules to this service for all of the same reasons it opposes any separation requirements for out-of-region services. BellSouth contends that the other interpretation—BOC's offering interexchange, CMRS—constitutes ''incidental'' CMRS interLATA services and is beyond the scope of this proceeding. To the extent that a CMRS provider offers interexchange services in conjunction with its provision of CMRS, the interexchange service is itself incidental CMRS, and thus exempted from section 272 separate affiliate requirements, according to BellSouth. Bell Atlantic and SBC also oppose any restrictions on BOC provision of incidental interLATA services, including CMRS, because most of these services were excluded from the separate subsidiary requirement of 272.

43. MCI contends that the scope of Section 272 is irrelevant because the 1996 Act does not prevent the Commission from imposing its own separation requirements. Vanguard supports the proposed separation

requirements on the assumption that they will be applied to BOC provision of interLATA services to the customers of its affiliated cellular companies. Vanguard argues that the interest that a BOC has in its cellular operations increases the incentives to engage in anticompetitive conduct because such conduct can benefit both its long distance operations and its cellular operations. Comptel urges the Commission to apply to all incidental interLATA services the same rules applied to out-of-region interexchange services because they raise the same concerns about discrimination and cross-subsidization.

44. BellSouth's interpretation of our reference to CMRS in footnote two of the *BOC Out-of-Region NPRM* is correct. Our statement in the *BOC Out-of-Region NPRM* was intended to clarify that a BOC offering out-of-region long distance service to unaffiliated CMRS customers on a stand alone basis would be considered ''out-of-region'' services for purposes of this rulemaking. BOC provision of interexchange services to its affiliated CMRS customers is beyond the scope of this proceeding. We also reject as beyond the scope of this proceeding Comptel's request to apply the separation requirements to all ''incidental'' services established under section 272(g).

B. Definition of Certain Services as In-Region Services

45. Section 271(j) provides that certain calls that originate out-of-region will be deemed in-region traffic. Specifically, this section provides that ''a [BOC] application to provide 800 service, private line service, or their equivalents that terminate in an in-region State of that [BOC], and allow the called party to determine the interLATA carrier, shall be considered an in-region service subject to the requirements of subsection (b)(1).''

46. Comptel argues that the Commission should declare collect and third party billed calls to numbers terminating in the BOC's region and BOC calling card calls to in-region numbers as ''equivalent'' services and thus be deemed in-region services. Comptel's rationale is that, like 800 number and private line services, the party paying for the call selects the interLATA carrier and thus is subject to the BOCs' local power. Comptel states that the Commission should therefore prohibit the BOC out-of-region affiliate from completing collect calls, third-party billed calls, or BOC calling card calls to terminating numbers located within the BOC's region. Ameritech opposes Comptel's interpretation, and asserts that calling card, collect and third party calls that are placed from out-of-region do not fall within 271(j) because the calling party, not the called party, determines the long distance carrier. Ameritech states that the calling party decides whether to complete the call on a 0+ basis or use access codes, and if access codes are used, the calling party decides which carrier to use.

47. The key factor in determining whether a service falls within the scope of section 271(j) as ''equivalent'' to 800 or private line service is whether the *called* party determines the interLATA carrier that is used. As Ameritech notes, calling card, collect and third party billed calls that originate out-of-region and terminate in-region do not fall within the scope of section 271(j) because it is the *calling* party, not the called party, that determines the interLATA carrier. Because the called party does not determine the interLATA carrier that is used, there is no justification for treating such calls as in-region services. Thus, we reject Comptel's proposal that we add calling card, collect and third party calls to those services classified as ''in-region'' under section 271(j).

V. Procedural Issues

A. Regulatory Flexibility Act Analysis

48. We certify that the Regulatory Flexibility Act is not applicable to the interim rules we are adopting in this proceeding. These interim rules will not result in a significant economic impact on a substantial number of small business entities, as defined by Section 601(3) of the Regulatory Flexibility Act. Entities subject to the rule changes are generally large corporations, affiliates of large corporations, or are dominant in their fields of operation, and, thus, are not ''small entities'' as defined by the Act. *See* 15 U.S.C. § 632(a)(1). We are nevertheless committed to reducing the regulatory burdens on small communications services companies whenever possible, consistent with our other public interest responsibilities. The Secretary shall send a copy of this Report and Order to the Chief Counsel for Advocacy of the Small Business Administration in accordance with Section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. §§ 601, *et seq.* (1981).

B. Paperwork Reduction Act

49. The recordkeeping requirements in this item are contingent upon approval of the Office of Management and Budget.

VI. Ordering Clause

50. Accordingly, *it is ordered* that, pursuant to Sections 1, 4, 201–205, 215, 218, 220, and 271 of the Communications Act of 1934, as amended, 47 U.S.C. §§ 151, 154, 201–205, 215, 218 and 220, the REPORT AND ORDER is hereby ADOPTED. The requirements adopted in this Report and Order shall be effective 30 days after publication in the Federal Register.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 96–17404 Filed 7–8–96; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 630

[I.D. 062796B]

Atlantic Swordfish Fishery; Drift Gillnet Closure

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration, Commerce.

ACTION: Closure.

SUMMARY: NMFS closes the drift gillnet fishery for swordfish in the Atlantic Ocean, including the Gulf of Mexico and Caribbean Sea. NMFS has determined that the adjusted second semiannual subquota for swordfish that may be harvested by drift gillnet will be reached on or before July 17, 1996. This closure is necessary to prevent exceeding the quota of swordfish caught by drift gillnet vessels.

EFFECTIVE DATE: 2330 hours, local time, July 17, 1996, through 2400 hours, local time, November 30, 1996.

FOR FURTHER INFORMATION CONTACT: Ronald G. Rinaldo, 301-713- 2347.

SUPPLEMENTARY INFORMATION: The Atlantic swordfish fishery is managed under the authority of the Magnuson Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*) and the Atlantic Tunas Convention Act (16 U.S.C. 971 *et seq.*).

The implementing regulations at 50 CFR 630.24(b)(3)(ii) establish a quota of swordfish that may be harvested by drift gillnet during the period July 1 through November 30, each year. Under 50 CFR 630.25(a), NMFS is required to close the drift gillnet fishery for swordfish when its quota is reached, or is projected to be reached, by filing a closure

announcement with the Office of the Federal Register at least 14 days before the closure is to become effective.

The 1996 swordfish Total Allowable Catch (TAC) allows for an Atlantic swordfish drift gillnet subquota of 22.5 mt dressed weight (49,603.5 lb) for the January 1 to June 30 period, and a subquota of 23.45 mt dressed weight (51,697.8 lb) for the July 1 to November 30 period. Our estimates indicate that only approximately 18,000 lb (8.164 mt) was caught during the first period subquota. The remaining portion of the first period subquota will be rolled over to the second period, for an adjusted second period subquota of 37.785 mt dressed weight, or 83,301.3 lb.

Based on the current level of swordfish catch by drift gillnets and historic data on catch per set for July, NMFS has determined that the drift gillnet quota for the July 1 through November 30 period will be reached on or before July 17, 1996. Hence, the drift gillnet fishery for Atlantic swordfish is closed effective 2330 hours, local time, July 17, 1996, through 2400 hours, local time, November 30, 1996.

During this closure of the drift gillnet fishery: 1) no one aboard a vessel using or having onboard a drift gillnet may fish for swordfish from the North Atlantic swordfish stock; 2) no more than two swordfish per trip may be possessed on board vessel using or having onboard a drift gill net in the North Atlantic Ocean, including the Gulf of Mexico and Caribbean Sea, north of 5° N. lat., or landed in an Atlantic, Gulf of Mexico, or Caribbean coastal state.

Classification

This action is required by 50 CFR 630.25(a) and is exempt from review under E.O. 12866.

Dated: July 2, 1995.

Richard W. Surdi,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 96–17350 Filed 7–03–96; 11:47 am]

BILLING CODE 3510–22–F

Proposed Rules

Federal Register
Vol. 61, No. 132
Tuesday, July 9, 1996

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 Part 890

RIN 3206–AH46

Federal Employees Health Benefits Program: Opportunities to Enroll and Change Enrollment

AGENCY: Office of Personnel Management.

ACTION: Proposed rule.

SUMMARY: The Office of Personnel Management (OPM) is issuing proposed regulations to simplify and clarify the existing Federal Employees Health Benefits (FEHB) Program regulations concerning opportunities to enroll and change enrollment. The proposed regulations would make it easier for employing offices to determine whether circumstances permit individuals to enroll or change enrollment, and would result in a reduced potential for error and improved customer service.

DATE: We must receive comments on or before September 9, 1996.

ADDRESSES: Send written comments to Lucretia F. Myers, Assistant Director for Insurance Programs, Retirement and Insurance Service, Office of Personnel Management, P.O. Box 57, Washington, DC 20044, or deliver to OPM, Room 3451, 1900 E Street NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Barbara Myers (202) 606–0004.

SUPPLEMENTARY INFORMATION: The events that permit individuals to enroll for FEHB coverage or change enrollment are specified in regulation. When the FEHB Program first began over thirty years ago, there were few events that permitted individuals to enroll or change their enrollment. Since then, additional events have been added to accommodate changes to FEHB law, establishment of other Federal programs that affected Federal employees and retirees, and changes in the personal circumstances of employees and annuitants.

Among the changes to FEHB law have been (1) extending FEHB coverage to certain former spouses and temporary employees, (2) providing temporary continuation of coverage (TCC) for enrollees and family members who lose coverage under certain conditions, and (3) prorating of premiums for part-time employees. Some other Federal programs that have been established since the FEHB Program began that affect Federal employees and retirees are Medicare and the Federal Employees Retirement System (FERS). Also, to adapt to changes in the personal circumstances of employees and annuitants, FEHB regulations now permit enrollment upon loss of non-Federal coverage under certain conditions.

The inquiries we receive from the White House, Members of Congress, Federal agencies, employees, and other individuals indicate that it is becoming increasingly difficult for employing offices to locate and interpret the appropriate regulation when an individual request to enroll or change his or her enrollment. In addition, when an employing office denies a request because they do not believe the circumstances comply with the regulations, the individual usually asks for reconsideration of that decision.

OPM has issued final regulations (59 FR 66434, December 27, 1994) that delegate to Federal agencies the authority to reconsider disputes over coverage and enrollment and to make retroactive as well as prospective corrections of administrative errors. Our proposed regulations would also give agencies the authority to correct enrollee errors under certain circumstances. We believe that these proposed regulations would help to reduce both the number of agency denial of enrollee requests and the volume of reconsideration requests.

More specifically, we believe these proposed regulations would improve administration of the FEHB Program by:

1. Organizing the opportunities to enroll and change enrollment into separate sections for employees, annuitants, former spouses, and those on Temporary Continuation of Coverage. This would reduce the time it takes for the employing office to locate the regulation applicable to the individual that is being assisted.

2. Grouping several of the enrollment opportunities within each section by similar characteristics, such as opportunities based on a change in employment status, or a loss of health benefits coverage. This further organization of the events would make it easier for the reader to locate the event that is needed.

3. Standardizing as much as possible the timeframes for individuals to enroll or change enrollment. In some cases the existing timeframe will increase from 31 to 60 days after the event. In other situations the timeframe will be extended to include a period before the event as well as after. This standardization would reduce the number of belated enrollment requests the employing offices receive, and help to assure continuous coverage for employees and family members whose eligibility to enroll in FEHB or change enrollment is based on a loss of other coverage.

4. Locating effective date information within the paragraph that describes the enrollment or change opportunity. Current regulations provide information on enrollment opportunities in one section and their corresponding effective dates in another. This revision would improve processing by making it easier for the reader to determine the appropriate effective date for a specific enrollment or change opportunity.

5. Clarifying some of the opportunities by removing certain hard to define requirements that individuals must meet to become eligible to enroll or change enrollment. This increased flexibility would make it easier for employees to provide FEHB coverage for their eligible children. It would also make it easier for agencies to make enrollment decisions, and reduce the number of agency denials of requests to enroll or change enrollment. Several examples of the clarified opportunities include:

a. Under current regulations (paragraph 890.301(y)), an employee may enroll, and an employee or annuitant may change enrollment when the employee or a family member involuntarily loses coverage under a non-Federal health plan. This requirement has generated numerous questions, denials, and reconsideration request about whether the loss of non-Federal coverage in a specific situation is voluntary or involuntary. To make it

easier for families to continue their health insurance protection upon loss of non-Federal coverage, we are no longer requiring agencies to determine what constitutes an involuntary loss of non-Federal coverage. We also are extending to enrollees covered under the former spouse and TCC provisions the opportunity to change from a self-only to self and family enrollment when an eligible family member loses non-Federal coverage.

b. Current regulations (paragraph 890.301(e)) permit an employee to enroll upon a change in marital status, but not upon any other change in family status. We recognize that in some situations an employee may have a change in family status without a change in marital status. Such situations may include (1) birth or acquisition of a child; (2) issuance of a court order specifically requiring an employee to enroll for his or her children or provide health benefits protection for them; (3) issuance or termination of a court order granting interlocutory divorce, limited divorce, legal separation, or separate maintenance to the enrollee or spouse; (4) entry into or discharge from military service of a spouse or of a child under age 22. Therefore, we are expanding this regulation to also permit an employee to enroll upon any other change in family status.

Under current regulations, a new enrollment takes effect at the beginning of the pay period after the enrollment request is received by the employing office and that follows a pay period during any part of which the employee is in pay status. We recognize that in some situations, the birth or acquisition of a child may occur while an employee is in a leave without pay status. Therefore, in this situation only, we are allowing the enrollment to take effect on the first day of the pay period in which the child is born or becomes an eligible family member, regardless of whether the enrollee was in a pay status the previous pay period.

c. Under current regulations (paragraph 890.301(g)(4)), an employee, annuitant, or former spouse who qualifies for FEHB coverage under section 890.803, who loses coverage because of cancellation of the covering enrollment must enroll in the same plan and option as that from which coverage was lost. We recognize that there may be situations in which the individual enrolled for self and family cancels the enrollment but the family member who loses coverage does not want to enroll in the same plan; or the enrollee of a prepaid plan cancels the enrollment but the family member who loses coverage lives in a different geographic location. As part of our effort to accommodate the complex family situations that can occur, we are eliminating this requirement and permitting enrollment in any plan or option when coverage is lost because the covering enrollment has been cancelled.

d. Current regulations (paragraph 890.301(t)) permit an employee to enroll if his or her coverage under the Medicaid program (State program of medical assistance for the needy) should terminate. They also permit an employee who is enrolled for self only to change to a self and family enrollment if a family member loses Medicaid coverage. Under our proposed regulations, an employee who is not enrolled may enroll if a family member should lose Medicaid coverage. Enrollees covered under the former spouse and TCC provisions may change from self only to self and family if an eligible family member loses Medicaid coverage. We also are extending to annuitants and former spouses who cancel their enrollment because they qualify for Medicaid coverage the opportunity to reenroll in the FEHB Program upon loss of the Medicaid coverage.

e. Under current regulations (paragraph 890.301(h)), an enrollee in a comprehensive medical plan who loses coverage or access to health services because of a change of address or place of employment may change enrollment. The enrollee must provide the employing office with written notification of his or her move or employment change or ''satisfactory'' evidence of a family member's move. To accommodate alternative and more automated systems of processing enrollment changes, and to make it easier for agencies to process enrollment changes under this event, we are removing the written notification requirement and no longer requiring agencies to determine what constitutes ''satisfactory'' evidence.

As part of our continuing effort to improve service to FEHB enrollees, we are revising paragraph 890.302(f) concerning determinations of incapacity for children over age 22. Under FEHB law, a child's coverage ends at age 22 unless the child is determined incapable of self-support because of a physical or mental disability that existed before age 22. Since current regulations require the employing office (the retirement system is the employing office for annuitants) to make determinations of incapacity, enrollees who contact their insurance carrier to request continued coverage for a disabled child are referred back to the employing office. There are certain medical conditions that would cause children to be incapable of self-support during adulthood, and if a child has one of these conditions, we believe that carriers should be able to extend coverage without going back to the employing agency. Therefore, we are revising the regulations to permit either the employing office or the carrier to make determinations of incapacity in such cases. We will provide an up-to-date list of these medical conditions in a Benefits Administration Letter and an FEHBP Letter to All Carriers; if we need to add or delete a condition in the future, we will notify employing offices and carriers promptly by means of these publications. If a child has a medical condition that is not on the list, the employing office will continue to make the determination.

We also will be adding the term ''appropriate request'' to our definitions. This new definition will allow for alternative and more automated methods of processing enrollments. These methods, which include Employee Express, should result in faster enrollment processing and improved customer service.

Finally, we will be making a conforming change to paragraph 890.803(a)(3)(i) to correct a reference to § 831.606, which has been redesignated as § 831.613.

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because they primarily affect Federal employees, annuitants, and former spouses.

List of Subjects in 5 CFR Part 890

Administrative practice and procedure, Government employees, Health facilities, Health insurance, Health professions, Hostages, Iraq, Kuwait, Lebanon, Reporting and recordkeeping requirements, Retirement.

U.S. Office of Personnel Management.

James B. King,

Director.

Accordingly, OPM proposes to amend 5 CFR Part 890 as follows:

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 § 890.101, paragraph (a), the definitions for *Enrolled* and *Enrollee* are

revised, the definitions for *Cancellation, Change of enrollment, Register,* and *Register to enroll* are removed, and the definitions for *Appropriate request, Cancel, Change the enrollment,* and *Enroll* are added in alphabetical order to read as follows:

§ 890.101 Definitions; time computations.

(a) * * *

Appropriate request means a properly completed health benefits registration form or an alternative method acceptable to both the employing office and OPM. Alternative methods must be capable of transmitting to the health benefits plans the information they require before accepting an enrollment. In addition, for an enrollment or cancellation to be valid, the signature of the requesting individual must be on the request, or on a form from the employing office that notifies the requesting individual of the enrollment or cancellation and requests his or her confirmation. For changes of enrollments, the signature of the requesting individual is not required but the employing office must promptly give the requesting individual notice of the change of enrollment. For purposes of § 890.301, electronic signatures, including the use of Personal Identification Numbers (PIN), have the same validity as a written signature.

* * * * *

Cancel means to submit to the employing office an appropriate request electing not to be enrolled by an enrollee who is eligible to continue enrollment.

Change the enrollment means to submit to the employing office an appropriate request electing a change of enrollment to a different plan or option, or to a different type of coverage (self only or self and family).

* * * * *

Enroll means to submit to the employing office an appropriate request electing to be enrolled in a health benefits plan.

Enrolled means an appropriate request has been accepted by the employing office and the enrollment in a health benefits plan approved by OPM under this part has not been terminated or canceled.

Enrollee means the individual in whose name the enrollment is carried. The term includes employees, annuitants, former employees, former spouses, or children who are enrolled after completing an appropriate request under the provisions of §§ 890.301, 890.306, 890.601, 890.803, or 890.1103 or have continued an enrollment as an annuitant or survivor annuitant under 5 U.S.C. 8905(b) or § 890.303.

* * * * *

3. In § 890.103, paragraphs (c) and (d) are redesignated as (d) and (e), and a new paragraph (c) is added to read as follows:

§ 890.103 Correction of errors.

* * * * *

(c) The employing office may make retroactive correction of enrollee enrollment code errors if the enrollee reports the error by the end of the pay period following the one in which he or she received the first written documentation (i.e. pay statement or enrollment change confirmation) indicating the error.

* * * * *

4. Section 890.301 is revised to read as follows:

§ 890.301 Opportunities for employees to enroll or change enrollment; effective dates.

(a) *Initial opportunity to enroll.* An employee who becomes eligible may elect to enroll or not to enroll within 60 days after becoming eligible.

(b) *Effective date—generally.* Except as otherwise provided, an enrollment or change of enrollment takes effect on the first day of the first day period that begins after the date the employing office receives an appropriate request to enroll or change the enrollment and that follows a pay period during any part of which the employee is in pay status.

(c) *Belated enrollment.* When an employing office determines that an employee was unable, for cause beyond his or her control, to enroll or change the enrollment within the time limits prescribed by this section, the employee may enroll or change the enrollment within 60 days after the employing office advises the employee of its determination.

(d) *Enrollment by proxy.* Subject to the discretion of the employing office, an employee's representative, having written authorization to do so, may enroll or change the enrollment for the employee.

(e) *Change to self only.* (1) An employee may change the enrollment from self and family to self only at any time.

(2) A change of enrollment to self only takes effect on the first day of the first pay period after the employing office receives an appropriate request to change the enrollment, except that at the request of the employee and upon a showing satisfactory to the employing office that there was no family member eligible for coverage by the family enrollment, the employing office may make the change effective on the first day of the pay period following the one in which there was no family member.

(f) *Open season.* (1) An open season will be held each year from the Monday of the second full workweek in November through the Monday of the second full workweek in December.

(2) The Director of OPM may modify the dates specified in paragraph (f)(1) of this section or hold additional open seasons.

(3) During an open season, an eligible employee may enroll and an enrolled employee may change the enrollment from self only to self and family, from one plan or option to another, or make any combination of these changes.

(4)(i) An open season new enrollment takes effect on the first day of the first pay period that begins in the next following year and which follows a pay period during any part of which the employee is in a pay status.

(ii) An open season change of enrollment takes effect on the first day of the first pay period which begins in January of the next following year.

(5) When a belated open season enrollment or change of enrollment is accepted by the employing office under paragraph (c) of this section, it takes effect as required by paragraph (f)(4) of this section.

(g) *Change in family status.* (1) An eligible employee may enroll and an enrolled employee may change the enrollment from self only to self and family, from one plan or option to another, or make any combination of these changes when the employee's family status changes, including a change in marital status or any other change in family status. The employee must enroll or change the enrollment within the period beginning 31 days before the date of the change in family status, and ending 60 days after the date of the change in family status.

(2) An enrollment or change of enrollment made in conjunction with the birth of a child, or the addition of a child as a new family member in some other manner, takes effect on the first day of the pay period in which the child is born or becomes an eligible family member.

(h) *Change in employment status.* An eligible employee may enroll and an enrolled employee may change the enrollment from self only to self and family, from one plan or option to another, or make any combination of these changes when the employee's employment status changes. Except as otherwise provided, an employee must enroll or change the enrollment within 60 days after the change in employment status. Employment status changes include, but are not limited to—

(1) A return to pay status following loss of coverage under § 890.304(a)(1)(v) due to the expiration of 365 days in leave without pay (LWOP) status.

(2) Reemployment after a break in service of more than 3 days.

(3) Restoration to a civilian position under part 353 of this chapter or other similar authority after being ordered to duty in a uniformed service for 31 days or more.

(4) A change from a temporary appointment in which the employee is eligible to enroll under 5 U.S.C. 8906a, which requires payment of the full premium with no Government contribution, to an appointment that entitles the employee to receive the Government contribution.

(5) Separation from Federal employment when the employee or the employee's spouse is pregnant and the employee supplies medical documentation of the pregnancy. An employee who enrolls or changes the enrollment under this paragraph (h)(5) must do so during his or her final pay period. The effective date of an enrollment or a change of enrollment under this paragraph is the first day of the pay period in which the employing office receives an appropriate request to enroll or change the enrollment.

(6) A transfer from a post of duty within a State of the United States or the District of Columbia to a post of duty outside a State of the United States or the District of Columbia, or the reverse. An employee enrolling under this paragraph (h)(6) must enroll or change the enrollment within the period beginning 31 days before leaving the old post of duty and ending 60 days after arriving at the new post of duty.

(7) A change, without a break in service or after a separation of 3 days or less, to part-time career employment as defined in 5 U.S.C. 3401(2) and 5 CFR part 340, subpart B, or a change from such part-time career employment to full-time employment that entitles the employee to the full Government contribution.

(i) *Loss of coverage under this part or under another group insurance plan.* An eligible employee may enroll and an enrolled employee may change the enrollment from self only to self and family, from one plan or option to another, or make any combination of these changes when the employee or an eligible family member of the employee loses coverage under this part or another group health benefits plan. Except as otherwise provided, an employee must enroll or change the enrollment within the period beginning 31 days before the date of loss of coverage, and ending 60 days after the date of loss of coverage. Losses of coverage include, but are not limited to—

(1) Loss of coverage under another FEHB enrollment due to the termination, cancellation, or a change to self only, of the covering enrollment.

(2) Loss of coverage under another federally-sponsored health benefits program.

(3) Loss of coverage or loss of access to health services because the employee or a covered family member in a comprehensive medical plan moves or becomes employed outside the enrollment or service area, or, if already outside the enrollment or service area, moves or becomes employed further from the enrollment or service area. The employee may change the enrollment upon notifying the employing office of the move or change of place of employment. The change of enrollment takes effect on the first day of the pay period that begins after the employing office receives an appropriate request.

(4) Loss of coverage due to the termination of membership in an employee organization sponsoring or underwriting an FEHB plan.

(5) Loss of coverage due to the discontinuance of an FEHB plan in whole or in part. For an employee who loses coverage under this paragraph (i)(5):

(i) If the discontinuance is at the end of a contract year, the employee must change the enrollment during the open season, unless OPM establishes a different time. If the discontinuance is at a time other than the end of the contract year, OPM must establish a time and effective date for the employee to change the enrollment.

(ii) If the whole plan is discontinued, an employee who does not change the enrollment within the time set is considered to have cancelled the plan in which enrolled.

(iii) If one option of a plan that has two options is discontinued, an employee who does not change the enrollment is considered to be enrolled in the remaining option of the plan.

(6) Loss of coverage under the Medicaid program (State program of medical assistance for the needy).

(7) Loss of coverage under a non-Federal health plan because an employee moves out of the commuting area to accept another position and the employee's non-federally employed spouse terminates employment to accompany the employee. An employee may enroll or change the enrollment within the period beginning 31 days before the date the employee leaves employment in the old commuting area and ending 180 days after entry on duty at place of employment in the new commuting area.

(8) Loss of coverage under a non-Federal health plan.

(j) *On becoming eligible for Medicare.* An employee may change the enrollment from one plan or option to another at any time beginning on the 30th day before becoming eligible for coverage under title XVIII of the Social Security Act (Medicare). A change of enrollment based on becoming eligible for Medicare may be made only once.

(k) *Salary of temporary employee insufficient to pay withholdings.* If the salary of a temporary employee eligible under 5 U.S.C. 8906a is not sufficient to pay the withholdings for the plan in which the employee is enrolled, the employing office shall notify the employee of the plans available at a cost that does not exceed the employee's salary. The employee may enroll in another plan whose cost is no greater than his or her salary within 60 days after receiving such notification from the employing office. The change of enrollment takes effect immediately upon termination of the prior enrollment.

5. In § 890.302, paragraph (f) is revised to read as follows:

§ 890.302 Coverage of family members.

* * * * *

(f) *Determination of incapacity.* (1) Except as provided in paragraph (f)(2) of this section, the employing office shall make determinations of incapacity.

(2) Either the employing office or the carrier may make a determination of incapacity if a medical condition, as specified by OPM, exists that would cause a child to be incapable of self-support during adulthood.

* * * * *

6. In § 890.303, paragraph (a)(1) is amended by removing ''registration'' and adding in its place ''enrollment'', and paragraph (a)(3) is revised to read as follows:

§ 890.303 Continuation of enrollment.

(a) * * *

(3) For the purpose of this part, an employee is considered to have enrolled at his or her first opportunity if the employee enrolled during the first of the periods set forth in § 890.301 in which he or she was eligible to enroll or was covered at that time by the enrollment of another employee or annuitant, or whose enrollment was effective not later than December 31, 1964.

* * * * *

(7) In § 890.304, paragraph (a)(2) is amended by removing ''§ 890.301(ee)'' and adding in its place ''§ 890.301 (k)'', paragraph (b)(1) is amended by

removing ''§ 890.301 (q)'' and adding in its place ''§ 890.306 (o)'', and the first two sentences of paragraph (d) are revised to read as follows:

§ 890.304 Termination of enrollment.

* * * * *

(d) *Cancellation.* Except an provided in ''§ 890.807(e), an enrollee may cancel his or her enrollment at any time by filing an appropriate request with the employing office. The cancellation takes effect on the last day of the pay period in which the appropriate request canceling the enrollment is received by the employing office, except that the cancellation of an enrollee having a monthly or 4-weekly pay period takes effect at the end of the pay period in which the appropriate request is received if the request is received between the first and fifteenth day of the pay period.* * *

* * * * *

8. Section 890.306 is revised to read as follows:

§ 890.306 Opportunities for annuitants to change enrollment or to reenroll; effective dates.

(a) *Requirements to continue coverage.* (1) To be eligible to continue coverage in a plan under this part, a former employee in receipt of an annuity must meet the statutory requirements under 5 U.S.C. 8905(b) of having retired on an immediate annuity and having been covered by a plan under this part for the 5 years of service immediately before retirements, or if less than 5 years, for all service since his or her first opportunity to enroll, unless OPM waives the requirement under § 890.108.

(2) To be eligible to continue coverage in a plan under this part, a survivor annuitant must be covered as a family member when the employee or annuitant dies.

(b) *Effective date—generally.* Except as otherwise provided, an annuitant's change of enrollment takes effect on the first day of the first pay period that begins after the date the employing office receives an appropriate request to change the enrollment.

(c) *Belated enrollment.* When an employing office determines that an annuitant was unable, for clause beyond his or her control, to continue coverage by enrolling in his or her own name or change the enrollment within the time limits prescribed by this section, the annuitant may do so within 60 days after the employing office advises the annuitant of its determination.

(d) *Enrollment by proxy.* Subject to the discretion of the empoloying office, an annuitant's representative, having written authorization to do so, may continue the annuitant's coverage by enrolling in the annuitant's own name, or change the enrollment for the annuitant.

(e) *Change to self only.* (1) An annuitant may change the enrollment from self and family to self only at any time.

(2) A change of enrollment to self only takes effect on the first day of the first pay period after the employing office receives an appropriate request to change the enrollment, except that at the request of the annuitant and upon a showing satisfactory to the employing office that there was no family member eligible for coverage under the family enrollment, the employing office may make the change effective on the first day of the pay period following the one in which was no family member.

(f) *Open season.* (1) During an open season as provided by § 890.301(f)—

(i) An enrolled annuitant may change the enrollment from self only to self and family, from one plan or option to another, or make any combination of these changes.

(ii) An annuitant who cancelled the enrollment under this part for the purpose of enrolling in a prepaid health plan under sections 1833 or 1876 of the Social Security Act, and who subsequently voluntarily disenrolls from the prepaid health plan, may reenroll.

(iii) An annuitant who cancelled the enrollment under this part because he or she furnished proof of eligibility for coverage under the Medicaid program (State program of medical assistance for the needy), and who wishes to reenroll in a plan under this part for reasons other than an involuntary loss of Medicaid coverage, may do so.

(2) An open season reenrollment or change of enrollment takes effect on the first day of the first pay period that begins in January of the next following year.

(3) When a belated open season reenrollment or change of enrollment is accepted by the employing office under paragraph (c) of this section, it takes effect as required by paragraph (f)(2) of this section.

(g) *Change in family status.* (1) An enrolled former employee in receipt of an annuity may change the enrollment from self only to self and family, from one plan or option to another, or make any combination of these changes when the annuitant's family status changes, including a change in marital status or any other change in family status. In the case of an enrolled survivor annuitant, a change in family status based on additional family members occurs only if the additional family members are family members of the deceased employee or annuitant. The annuitant must change the enrollment within the period beginning 31 days before the date of the change in family status, and ending 60 days after the date of the change in family status.

(2) A change of enrollment made in conjunction with the birth of a child, or the addition of a child as a new family member in some other manner, takes effect on the first day of the pay period in which the child is born or becomes an eligible family member.

(h) *Reenrollment of annuitants who cancelled enrollment to enroll in a Medicare-sponsored Coordinated Care Plan.* (1) An annuitant who had been enrolled (or was otherwise eligible to enroll) for coverage under this part and cancelled the enrollment for the purpose of enrolling in a prepaid health plan under sections 1833 or 1876 of the Social Security Act (as provided by § 890.304(d)), and who is subsequently involuntarily disenrolled from the prepaid health plan, may immediately reenroll in any available plan under this part at any time beginning 31 days before and ending 60 days after the disenrollment. A reenrollment under this paragraph (h) takes effect on the date following the effective date of the disenrollment as shown on the documentation from the prepaid health plan.

(2) An annuitant who voluntarily disenrolls from the prepaid health plan must do so in conjunction with reenrolling in a plan under this part during the next available open season (as provided by paragraph (f) of this section) to assure continuing uninterrupted health plan coverage.

(i) *Reenrollment of annuitants who cancelled enrollment because of eligibility under the Medicaid program.* (1) An annuitant who had been enrolled (or was otherwise eligible to enroll) for coverage under this part and cancelled the enrollment because he or she furnished proof of eligibility for coverage under the Medicaid program (State program of medical assistance for the needy), and who involuntarily loses coverage under Medicaid, may reenroll in any available plan under this part at any time beginning 31 days before and ending 60 days after the loss of Medicaid coverage. A reenrollment under this paragraph (i) takes effect on the date following the date of loss of Medicaid coverage.

(2) An annuitant who cancelled his or her enrollment because he or she furnished proof of eligibility for Medicaid coverage, and who wishes to reenroll in a plan under this part for

reasons other than an involuntary loss of Medicaid coverage, may do so during the next available open season as provided by paragraph (f) of this section.

(j) *Annuitants who apply for postponed minimum retirement age plus 10 years of service (MRA plus 10) annuity.* (1) A former employee who meets the requirements for an immediate annuity under 5 U.S.C. 8412(g) and for continuation of coverage under 5 U.S.C. 8905(b) at the time of separation, and whose enrollment is terminated under § 890.304(a)(1)(ii) may enroll in a health benefits plan under this part within 60 days after OPM mails the former employee a notice of eligibility. If such former employee dies before the end of this 60-day election period, a survivor who is entitled to a survivor annuity may enroll in a health benefits plan under this part within 60 days after OPM mails the survivor a notice of eligibility.

(2) The former employee's enrollment takes effect on the first day of the month following the month in which OPM receives the appropriate request or on the commencing date of annuity, whichever is later. A survivor's enrollment takes effect on the first day of the month following the month in which OPM receives the appropriate request.

(k) *Restoration of annuity or compensation payments.* (1) A disability annuitant who was enrolled in a health benefits plan under this part immediately before his or her disability annuity was terminated because of restoration to earning capacity or recovery from disability, and whose disability annuity is restored under 5 U.S.C. 8337(e) after December 31, 1983, or 8455(b), may enroll in a health benefits plan under this part within 60 days after OPM mails a notice of insurance eligibility. The enrollment takes effect on the first day of the month after the date OPM receives the appropriate request.

(2) An annuitant who was enrolled in a health benefits plan under this part immediately before his or her compensation was terminated because the OWCP determined that he or she had recovered from the job-related injury or disease, and whose compensation is restored due to a recurrence of disability, may enroll in a health benefits plan under this part within 60 days after OWCP mails a notice of insurance eligibility. The enrollment takes effect on the first day of the pay period after the date OWCP receives the appropriate request.

(3) A surviving spouse who was covered by a health benefits enrollment under this part immediately before his or her survivor annuity was terminated because of remarriage, and whose survivor annuity is later restored, may enroll in a health benefits plan under this part within 60 days after OPM mails a notice of eligibility. The enrollment takes effect on either—

(i) The first day of the month after the date OPM receives the appropriate request; or

(ii) The date of restoration of the survivor annuity or October 1, 1976, whichever is later.

(4) A surviving child who was covered by a health benefits enrollment under this part immediately before his or her survivor annuity was terminated because he or she ceased being a student, and whose survivor annuity is later restored, may enroll in a health benefits plan under this part within 60 days after OPM mails a notice of eligibility. The enrollment takes effect on the first day of the month after the date OPM receives the appropriate request or the date of restoration of the survivor annuity, whichever is later.

(5) A surviving spouse who received a basic employee death benefit under 5 U.S.C. 8442(b)(1)(A) and who was covered by a health benefits enrollment under this part immediately before remarriage prior to age 55, may enroll in a health benefits plan under this part upon termination of the remarriage. The survivor must provide OPM with a certified copy of the notice of death or the court order terminating the marriage. The surviving spouse must enroll within 60 days after OPM mails a notice of eligibility. The enrollment takes effect on the first day of the month after the date OPM receives the appropriate request and the notice of death or court order terminating the remarriage.

(l) *Loss of coverage under this part or under another group insurance plan.* An annuitant who meets the requirements of paragraph (a) of this section, and who is not enrolled but is covered by another enrollment under this part may continue coverage by enrolling in his or her own name when the annuitant loses coverage under the other enrollment under this part. An enrolled annuitant may change the enrollment from self only to self and family, from one plan or option to another, or make any combination of these changes when the annuitant or an eligible family member of the annuitant losses coverage under this part or under another group health benefits plan. Except as otherwise provided, an annuitant must enroll or change the enrollment within the period beginning 31 days before the date of loss of coverage and ending 60 days after the date of loss of coverage. Losses of coverage include, but are not limited to—

(1) Loss of coverage under another FEHB enrollment due to the termination, cancellation, or a change to self only, of the covering enrollment;

(2) Loss of coverage under another federally-sponsored health benefits program;

(3) Loss of coverage or loss of access to health services because the annuitant or a covered family member in a comprehensive medical plan moves or becomes employed outside the enrollment or service area, or, if already outside the enrollment or service area, moves or becomes employed further from the enrollment or service area. The annuitant may change the enrollment upon notifying the employing office of the move or change of place of employment. The change of enrollment takes effect on the first day of the pay period that begins after the employing office receives an appropriate request.

(4) Loss of coverage due to the termination of membership in an employee organization sponsoring or underwriting an FEHB plan;

(5) Loss of coverage due to the discontinuance of an FEHB plan in whole or in part. For an annuitant who loses coverage under this paragraph (l)(5)—

(i) If the discontinuance is at the end of a contract year, the annuitant must change the enrollment during the open season, unless OPM establishes a different time. If the discontinuance is at a time other than the end of the contract year, OPM must establish a time and effective date for the annuitant to change the enrollment;

(ii) If a plan has only one option and is discontinued, an annuitant who does not change the enrollment is deemed to have enrolled in the standard option of the Blue Cross and Blue Shield Service Benefit Plan.

(iii) If a plan has two options, and one option of the plan is discontinued, an annuitant who does not change the enrollment is considered to be enrolled in the remaining option of the plan.

(iii) If a plan has two options and both options are discontinued, an annuitant who does not change the enrollment is deemed to have enrolled in the corresponding option of the Blue Cross and Blue Shield Service Benefit Plan. If the annuitant is enrolled in a high option and his or her annuity is insufficient to pay the withholding for the high option, the annuitant is deemed to have enrolled in the standard option of the Blue Cross and Blue Shield Service Benefit Plan. The exemptions from debt collection

procedures that are provided under sections 831.1305(d)(2) and 845.205(d)(2) of this chapter apply to elections under this paragraph;

(6) Loss of coverage under the Medicaid program (State program of medical assistance for the needy).

(7) Loss of coverage under a non-Federal health plan.

(m) *Overseas post of duty.* An annuitant may change the enrollment from self only to self and family, from one plan or option to another, or make any combination of these changes within 60 days after the retirement or death of the employee on whose service title to annuity is based, if the employee was stationed at a post of duty outside a State of the United States or the District of Columbia at the time of retirement or death.

(n) *On return from a uniformed service.* An enrolled annuitant who enters on duty in a uniformed service for 31 days or more may change the enrollment within 60 days after separation from the uniformed service.

(o) *On becoming eligible for Medicare.* An annuitant may change the enrollment from one plan or option to another at any time beginning on the 30th day before becoming eligible for coverage under title XVIII of the Social Security Act (Medicare). A change of enrollment based on becoming eligible for Medicare may be made only once.

(p) *Annuity insufficient to pay withholdings.* (1) If an annuity is sufficient to pay the withholdings for the plan that the annuitant is enrolled in, the retirement system must provide the annuitant with information regarding the available plans and written notification of the opportunity to either—

(i) Pay the premium directly to the retirement system in accordance with § 890.502(f); or

(ii) Enroll in any plan in which the annuitant's share of the premium is less than that amount of annuity. If the annuitant elects to change to a lower cost enrollment, the change takes effect immediately upon loss of coverage under the prior enrollment.

(2) If the annuitant is enrolled in the high option of a plan that has two options, and does not change the enrollment to a plan in which the annuitant's share of the premium is less than the amount of annuity or does not elect to pay premiums directly, the annuitant is deemed to have enrolled in the standard option of the same plan, unless the annuity is insufficient to pay the withholdings for the standard option.

(3) An annuitant whose enrollment was terminated because the amount of annuity was insufficient to cover the enrollee's share of the premium may apply to be reinstated in any available plan or option.

(4) An annuitant who can show evidence that he or she previously changed to a lower cost option, plan, or to a self only enrollment prior to May 29, 1990, because the annuity was insufficient to cover the withholdings for the plan in which he or she was enrolled, may apply to change the enrollment to any available plan or option in which the enrollee's share of the total premium exceeds his or her monthly annuity.

(5) The effective date of the reinstatement of enrollment of an annuitant whose enrollment was terminated, or the change of enrollment of an annuitant who previously changed enrollment because his or her annuity was insufficient to cover the annuitant's share of the total premium, and who elects to pay premiums directly to the retirement system in accordance with § 890.502(f) is either—

(i) The first day of the first pay period that begins after the appropriate request is received by the retirement system; or,

(ii) The later of the date the enrollment was terminated or changed, or May 29, 1990.

(6) Retroactive reinstatement or change of enrollment is contingent upon payment of appropriate contributions retroactive to the effective date of the reinstatement or the change of enrollment. For the purpose of this paragraph (p)(6), a previous cancellation of enrollment because of insufficient annuity to cover the full amount of the withholdings is deemed to be a termination of enrollment.

(q) *Sole survivor.* When an employee or annuitant enrolled for self and family dies, leaving a survivor annuitant who is entitled to continue the enrollment, and it is apparent from available records that the survivor annuitant is the sole survivor entitled to continue the enrollment, the office of the retirement system which is acting as employing office must change the enrollment from self and family to self only, effective on the commencing date of the survivor annuity. On request of the survivor annuitant made within 31 days after the first installment of annuity is paid, the office of the retirement system which is acting as employing office must rescind the action retroactive to the effective date of the change to self only, with corresponding adjustment in withholdings and contributions.

(r) *Election between survivor annuities.* A surviving spouse, irrespective of whether his or her survivor annuity continued or was terminated upon remarriage, who was covered by an enrollment under this part immediately before the remarriage, may elect to continue an enrollment under this part acquired as a dependent by virtue of the remarriage or to enroll in his or her own right (by virtue of entitlement to the original survivor annuity) in any plan or option under this part within 60 days after the termination of the remarriage and entitlement to a survivor annuity.

§ 890.602 [Amended]

9. Section 890.602 is amended by removing ''register'' and adding in its place ''elect to enroll''.

§ 890.803 [Amended]

10. In § 890.803, paragraph (a)(3)(i) is amended by removing ''5 CFR 831.606(a) and (b) and 842.605(a) and (b)'' and adding in its place ''§§ 831.613(a) and (b) and 842.605(a) and (b) of this chapter''.

11. Section 890.806 is revised to read as follows:

§ 890.806 Opportunities for former spouses to enroll and change enrollment; effective dates of enrollment.

(a) *Initial opportunity to enroll.* A former spouse who has met the eligibility requirements of § 890.803 and the application time limitation requirements of § 890.805 may enroll at any time after the employing office establishes that these requirements have been met.

(b) *Effective date—generally.* (1) Except as otherwise provided, an enrollment takes effect on the first day of the first pay period that begins after the date the employing office receives an appropriate request and satisfactory proof of eligibility as required by paragraph (a) of this section. If a former spouse requests immediate coverage, and the employing office receives an appropriate request and satisfactory proof of eligibility within 60 days after the date of divorce, the enrollment may be made effective on the same day that temporary continuation of coverage under subpart K of this part would otherwise take effect.

(2) A change of enrollment takes effect on the first day of the first pay period that begins after the employing office receives the appropriate request.

(c) *Belated enrollment.* When an employing office determines that a former spouse was unable, for cause beyond his or her control, to enroll or change the enrollment within the time limits prescribed by this section, the former spouse may do so within 60 days after the employing office advises the former spouse of its determination.

(d) *Enrollment by proxy.* Subject to the discretion of the employing office, a former spouse's representative, having written authorization to do so, may enroll or change the enrollment for the former spouse.

(e) *Change to self only.* (1) A former spouse may change the enrollment from self and family to self only at any time.

(2) A change of enrollment to self only takes effect on the first day of the first pay period after the employing office receives an appropriate request to change the enrollment, except that at the request of the former spouse and upon a showing satisfactory to the employing office that there was no family member eligible for coverage under the family enrollment, the employing office may make the change take effect on the first day of the pay period following the one in which there was no family member.

(f) *Open season.* (1) During an open season as provided by § 890.301(f)—

(i) An enrolled former spouse may change the enrollment from self only to self and family provided the family member(s) is eligible for coverage under § 890.804, from one plan or option to another, or make any combination of these changes.

(ii) A former spouse who cancelled the enrollment under this part for the purpose of enrolling in a prepaid health plan under sections 1833 or 1876 of the Social Security Act, and who subsequently voluntarily disenrolls from the prepaid health plan, may reenroll.

(iii) A former spouse who canceled the enrollment under this part because he or she furnished proof of eligibility for coverage under the Medicaid program (State program of medical assistance for the needy), and who wishes to reenroll in a plan under this part for reasons other than an involuntary loss of Medicaid coverage, may do so.

(2) An open season reenrollment or change of enrollment takes effect on the first day of the first pay period that begins in January of the next following year.

(3) When a belated open season reenrollment or change of enrollment is accepted by the employing office under paragraph (c) of this section, it takes effect as required by paragraph (f)(2) of this section.

(g) *Change in family status.* (1) An enrolled former spouse may change the enrollment from self only to self and family, from one plan or option to another, or make any combination of these changes within the period beginning 31 days before and ending 60 days after the birth or acquisition of a child who meets the eligibility requirements of § 890.804.

(2) A change in enrollment under paragraph (g)(1) of this section takes effect on the first day of the pay period in which the child is born or becomes an eligible family member.

(h) *Reenrollment of former spouses who canceled enrollment to enroll in a Medicare-sponsored Coordinated Care Plan.* (1) A former spouse who had been enrolled for coverage under this part and canceled enrollment for the purpose of enrolling in a prepaid health plan under sections 1833 or 1876 of the Social Security Act, and who is subsequently involuntarily disenrolled from the prepaid health plan, may immediately reenroll in any available plan under this part at any time beginning 31 days before and ending 60 days after the disenrollment. A reenrollment under this paragraph (h) takes effect on the date following the effective date of the disenrollment as shown on the documentation from the prepaid health plan.

(2) A former spouse who voluntarily disenrolls from the prepaid health plan must do so in conjunction with reenrolling in a plan under this part during the next available open season as provided by paragraph (f) of this section to assure continuing uninterrupted health plan coverage.

(i) *Reenrollment of former spouses who canceled enrollment because of eligibility under the Medicaid program.* (1) A former spouse who had been enrolled (or was otherwise eligible to enroll) for coverage under this part and canceled the enrollment because he or she furnished proof of eligibility for coverage under the Medicaid program (State program of medical assistance for the needy), and who involuntarily loses coverage under Medicaid, may reenroll in any available plan under this part at any time beginning 31 days before and ending 60 days after the loss of Medicaid coverage. A reenrollment under this paragraph (i) takes effect on the date following the date of loss of Medicaid coverage.

(2) A former spouse who canceled his or her enrollment because he or she furnished proof of eligibility for Medicaid coverage, and who wishes to reenroll in a plan under this part for reasons other than an involuntary loss of Medicaid coverage, may do so during the next available open season as provided by paragraph (f) of this section.

(j) *Loss of coverage under this part or under another group insurance plan.* A former spouse who has established eligibility for health benefits under § 890.803 and met the application time limitations of § 890.805, and who is not enrolled as a former spouse but is covered by another enrollment under this part or under another group health benefits plan, may enroll upon loss of the other coverage. An enrolled former spouse may change the enrollment from self only to self and family, from one plan or option to another or make any combination of these changes when the former spouse or a child who meets the eligibility requirements under § 890.804 loses coverage under another enrollment under this part or under another group health benefits plan. Except as otherwise provided, the former spouse must enroll or change the enrollment within the period beginning 31 days before and ending 60 days after the loss of coverage, provided he or she continues to meet the eligibility requirements under § 890.803. Losses of coverage include but are not limited to—

(1) Loss of coverage under another FEHB enrollment due to the termination, cancellation, or a change to self only, of the covering enrollment;

(2) Loss of coverage under another federally sponsored health benefits program;

(3) Loss of coverage or access to health services because the former spouse or a covered family member in a comprehensive medical plan moves or becomes employed outside the enrollment or service area, or, if already outside the enrollment or service area, moves or becomes employed further from the enrollment or service area. The former spouse may change the enrollment upon notifying the employing office of the move or change of place of employment. The change of enrollment takes effect on the first day of the pay period that begins after the employing office receives an appropriate request.

(4) Loss of coverage due to the termination of membership in an employee organization sponsoring or underwriting an FEHB plan;

(5) Loss of coverage due to the discontinuance of an FEHB plan in whole or in part. For a former spouse who loses coverage under this paragraph (j)(5)—

(i) If the discontinuance is at the end of a contract year, the former spouse must change the enrollment during the open season, unless OPM establishes a different time. If the discontinuance is at a time other than the end of the contract year, OPM must establish a time and effective date for the former spouse to change the enrollment;

(ii) If the whole plan is discontinued, a former spouse who does not change the enrollment within the time set is

considered to have cancelled the plan in which enrolled.

(iii) If one option of a plan that has two options is discontinued, a former spouse who does not change the enrollment is considered to be enrolled in the remaining option of the plan.

(6) Loss of coverage under the Medicaid program (State program of Medical assistance for the needy).

(7) Loss of coverage under a non-Federal health plan.

(k) *On becoming eligible for Medicare.* A former spouse may change the enrollment from one plan or option to another at any time beginning on the 30th day before becoming eligible for coverage under title XVIII of the Social Security Act (Medicare). A change of enrollment based on becoming eligible for Medicare may be made only once.

(1) *Annuity insufficient to pay withholdings.* (1) If the annuity of a former spouse is insufficient to pay the full subscription charge for the plan in which he or she is enrolled, the retirement system must provide the former spouse with information regarding the available plans and written notification of the opportunity to either—

(i) Pay the premium directly to the retirement system in accordance with § 890.808(d); or

(ii) Enroll in any plan with a full premium that is less than the amount of annuity. If the former spouse elects to change to a lower cost enrollment, the change takes effect immediately upon loss of coverage under the prior enrollment.

(2) If the former spouse is enrolled in the high option of a plan that has two options, and does not elect a plan with a full premium that is less than the annuity or does not elect to pay premiums directly, he or she is deemed to have enrolled in the standard option of the same plan unless the annuity is insufficient to pay the full subscription charge for the standard option.

(3) A former spouse who is enrolled in a plan with only one option, who fails to make the election required by this paragraph will be subject to the provisions of section 890.807(c).

(12) Section 890.807 is amended by revising the heading for paragraph (c) and revising paragraph (c)(1) to read as follows:

§ 890.807 Termination of enrollment.

* * * * *

(c) *Failure to make an election under § 890.806(l).* (1) If the annuity is insufficient to pay the full subscription charge due for the plan in which the former spouse is enrolled, the former spouse may elect one of the two opportunities offered under § 890.806(l) (electing a plan with a full subscription charge that is less than the annuity; or paying premiums directly to the retirement system in accordance with § 890.808(d). Except as provided in paragraph (c)(3) of this section the enrollment of a former spouse who fails to make an election within the specified time frame will be terminated.

* * * * *

13. In section 890.808, paragraph (e) is revised to read as follows:

§ 890.808 Employing office responsibilities.

* * * * *

(e) *Withholding from annuity.* The retirement system acting as employing office for a former spouse will establish a method for withholding the full subscription charge from the former spouse's annuity check. When the annuity is insufficient to cover the full subscription charge, the retirement system will follow the procedures specified in section 890.806(l).

14. Section 890.1105 is amended by revising the section heading and adding headings for paragraphs (b), (c), (d), and (f), by revising paragraphs (d) and (f), and by adding a new paragraph (g) to read as follows:

§ 890.11.05 Initial election of temporary continuation of coverage; application time limitations and effective dates.

* * * * *

(b) Former employees. * * *

(c) Children. * * *

(d) Former spouses. (a) A former spouse's election must be received by the employing office within 60 days after the later of—

(i) The date of the qualifying event; or

(ii) The date coverage under subpart H of this part was lost because of remarriage or loss of qualifying court order, if the loss of coverage under subpart H occurred before the expiration of the 36-month period specified in § 890.1107(c); or

(iii) If the employee or former spouse notified the agency of the termination of the marriage within the time period specified in § 890.1104(c)(1), the date the former spouse received the notice from the agency described in § 890.1104(c)(2). If neither the employee nor the former spouse notified the agency within the specified time period, the former spouse's opportunity to elect continued coverage ends 60 days after the qualifying event.

(2) The effective date of former spouse coverage is the later of—

(i) The date determined under paragraph (g) of this section; or

(ii) The date of the divorce or annulment.

* * * * *

(f) *Belated elections.* Except as provided in paragraphs (c)(2) and (d)(1)(iii) of this section, when an employing office determines that an eligible individual was unable, for cause beyond his or her control, to elect temporary continuation of coverage within the time limits prescribed by this section, that office must accept the election within 60 days after it advises the individual of that determination.

(g) *Effective date of coverage.* Except as provided in paragraph (d)(2)(ii) of this section, the effective date of temporary continuation of coverage is the day after other coverage under this part expires, including the 31-day temporary extension of coverage under § 890.401. If an individual elects temporary continuation of coverage after the 31-day temporary extension of coverage expires, but before the expiration of the applicable election period specified in this section, coverage is restored retroactively, with appropriate contributions and claims, to the same extent and effect as though no break in coverage occurred.

15. Section 890.1108 is revised to read as follows:

§ 890.1108 Opportunities to change enrollment; effective dates.

(a) *Effective date—generally.* Except as otherwise provided, a change of enrollment takes effect on the first day of the first pay period that begins after the employing office receives an appropriate request to change the enrollment.

(b) *Belated change of enrollment.* When an employing office determines that an enrollee was unable, for cause beyond his or her control, to change the enrollment within the time limits prescribed by this section, the enrollee may do so within 60 days after the employing office advises the enrollee of its determination.

(c) *Change of enrollment by proxy.* Subject to the discretion of the employing office, an enrollee's representative, having written authorization to do so, may change the enrollment for the enrollee.

(d) *Change to self only.* (1) An enrollee may change the enrollment from self and family to self only at any time.

(2) A change of enrollment to self only takes effect on the first day of the first pay period after the employing office receives an appropriate request to change the enrollment, except that at the request of the enrollee and upon a showing satisfactory to the employing office that there was no family member eligible for coverage under the family enrollment, the employing office may make the change effective on the first

day of the pay period following the one in which there was no family member.

(e) *Open season.* (1) During the open season as provided by § 890.301(f), an enrollee (except for a former spouse who is eligible for continued coverage under § 890.1103(3)) may change the enrollment from self only to self and family, from one plan or option to another, or make any combination of these changes. A former spouse who is eligible for continued coverage under § 890.1103(3) may change from one plan or option to another, but may not change from self only to self and family unless the individual to be covered under the family enrollment qualifies as a family member under § 890.1106(a)(2).

(2) An open season change of enrollment takes effect on the first day of the first pay period that begins in January of the next following year.

(3) When a belated open season change of enrollment is accepted by the employing office under paragraph (b) of this section, it takes effect as required by paragraph (e)(2) of this section.

(f) *Change in family status.* (1) Except for a former spouse, an enrollee may change the enrollment from self only to self and family, from one plan or option to another, or make any combination of these changes when the enrollee's family status changes, including a change in marital status or any other change in family status. The enrollee must change the enrollment within the period beginning 31 days before the date of the change in family status, and ending 60 days after the date of the change in family status.

(2) A former spouse who is covered under this section may change the enrollment from self alone to self and family, from one plan or option to another, or make any combination of these changes within the period beginning 31 days before and ending 60 days after the birth or acquisition of a child who qualifies as a covered family member under § 890.1106(a)(2).

(3) A change of enrollment made in conjunction with the birth of a child, or the addition of a child as a new family member in some other manner, takes effect on the first day of the pay period in which the child is born or becomes an eligible family member.

(g) *Reenrollment of individuals who lose other coverage under this part.* An individual whose continued coverage under this section terminates because of the provisions of § 890.1110(a)(3) (termination due to other coverage under another provision of this part) may reenroll if the coverage that terminated the enrollment under this part ends, but not later than the expiration of the period described in § 890.1107. Coverage does not extend beyond the expiration of the period described in § 890.1107. The effective date of the reenrollment is the day following the termination of the coverage described in § 890.1110(a)(3).

(h) *Loss of coverage under this part or under another group insurance plan.* An enrollee may change the enrollment from self only to self and family, from one plan or option to another, or make any combination of these changes when the enrollee loses coverage under this part or a qualified family member of the enrollee loses coverage under this part or under another group health benefits plan. Except as otherwise provided, an enrollee must change the enrollment within the period beginning 31 days before the date of loss of coverage and ending 60 days after the date of loss of coverage. Losses of coverage include, but are not limited to—

(1) Loss of coverage under another FEHB enrollment due to the termination, cancellation, or change to self only, of the covering enrollment.

(2) Loss of coverage under another federally-sponsored health benefits program.

(3) Loss of coverage or loss of access to health services because the enrollee or a covered family member in a comprehensive medical plan moves or becomes employed outside the enrollment or service area, or, if already outside the enrollment or service area, moves or becomes employed further from the enrollment or service area. The enrollee may change the enrollment upon notifying the employing office of the move or change of place of employment. The change of enrollment takes effect on the first day of the pay period that begins after the employing office receives an appropriate request.

(4) Loss of coverage due to the termination of membership in an employee organization sponsoring or underwriting an FEHB plan.

(5) Loss of coverage due to the discontinuance of an FEHB plan, in whole or in part. For an enrollee who loses coverage under this paragraph (h)(5)—

(i) If the discontinuance is at the end of a contract year, the enrollee must change the enrollment during the open season, unless OPM establishes a different time. If the discontinuance is at a time other than the end of the contract year, OPM must establish a time and effective date for the enrollee to change the enrollment.

(ii) If the whole plan is discontinued, an enrollee who does not change the enrollment within the time set is considered to have cancelled the plan in which enrolled;

(iii) If a plan has two options, and one option of the plan is discontinued, an enrollee who does not change the enrollment is considered to be enrolled in the remaining option of the plan.

(6) Loss of coverage under the Medicaid Program (State program of medical assistance for the needy).

(7) Loss of coverage under a non-Federal health plan.

(i) *On becoming eligible for Medicare.* An enrollee may change the enrollment from one plan or option to another at any time beginning on the 30th day before becoming eligible for coverage under title XVIII of the Social Security Act (Medicare). A change of enrollment based on becoming eligible for Medicare may be made only once.

[FR Doc. 96–17248 Filed 7–8–96; 8:45 am]
BILLING CODE 6325–01–M

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1280

[Docket Number LS–96–006]

Sheep Promotion, Research, and Information Program

AGENCY: Agricultural Marketing Service; USDA.

ACTION: Notice of Referendum; Referendum Order.

SUMMARY: The Agricultural Marketing Service (AMS) is announcing that a second referendum will be conducted among eligible sheep producers, sheep feeders, and importers of sheep and sheep products to determine whether the Sheep and Wool Promotion, Research, Education, and Information Order (Order) will become effective as authorized under the Sheep Promotion, Research, and Information Act of 1994 (Act). This action is a result of a review conducted by the Department of Agriculture (Department) that revealed that the referendum rules were applied inconsistently at the official polling places during the February 6, 1996, nationwide referendum. Consequently, the results of the February 6, 1996, nationwide referendum were voided.

DATES: Referendum Dates: In-person voting in the referendum will be conducted on October 1, 1996, by county Cooperative Extension Service (CES) offices. Absentee ballots will be available at county CES offices from August 26, 1996, through September 17, 1996. The representative period to establish voter eligibility will be the period from January 1, 1994, through December 31, 1994.

FOR FURTHER INFORMATION CONTACT: Ralph L. Tapp, Chief, Marketing Programs Branch, Livestock and Seed Division, AMS, USDA, Room 2606–S; P.O. Box 96456; Washington, D.C. 20090–6456. Telephone number 202/720–1115.

SUPPLEMENTARY INFORMATION: The Act (7 U.S.C. 7101–7111), enacted October 22, 1994, provides for the establishment of a national sheep and wool promotion, research, education, and information program, designed to strengthen the sheep industry's position in the marketplace, maintain and expand existing markets, and develop new markets and uses for sheep and sheep products.

The program will be funded by a mandatory assessment on domestic sheep producers, sheep feeders, and exporters of live sheep and greasy wool of 1 cent per pound on live sheep sold and 2 cents per pound on greasy wool sold. Importers will be assessed 1 cent per pound on live sheep imported and the equivalent of 1 cent per pound of live sheep for sheep products imported and 2 cents per pound of degreased wool or the equivalent of degreased wool for wool and wool products imported. Imported raw wool will be exempt from assessments. Each person who processes or causes to be processed sheep or sheep products of that person's own production, and who markets the processed products, will be assessed the equivalent of 1 cent per pound of live sheep sold and 2 cents per pound of greasy wool sold. All assessment rates may be adjusted in accordance with applicable provisions of the Act.

The Act requires that a referendum be conducted after an Order is issued to determine whether the Order will go into effect. An Order was published in the Federal Register on December 5, 1995 (60 FR 62298). The referendum is to be conducted among persons who were sheep producers, sheep feeders, or importers of sheep and sheep products during a representative period specified by the Secretary. Importers who import only raw wool are not eligible to participate in the referendum because raw wool is exempt from assessments under the Act. The Order would become operational only if it is approved by a majority of the producers, feeders, and importers voting in the referendum, or by producers, feeders, and importers voting in the referendum who account for at least two-thirds of the production represented by persons voting in the referendum. If the Order is not approved by persons voting in the referendum, the program will not become operational.

To vote in the referendum, eligible persons will complete the registration and certification form, mark their ballots and, if they want to vote according to their volume of production, record that number on the ballot. Producers, feeders, and importers who vote their volume of production must determine that number before they register and vote in the referendum. For producers and feeders, the volume of production is the largest number of head of domestic sheep owned for any single, consecutive, 30-day period during the representative period. For importers, the volume of production is the number of live sheep or live sheep equivalents imported during the representative period. The final referendum rules published in the Federal Register on December 15, 1995 (60 FR 64297), provide guidance for calculating import volume of production in sheep equivalents.

As required by the Act, the Department conducted an up-front referendum among eligible domestic sheep producers and sheep feeders, as well as importers of sheep and sheep products, to determine if the Order would become operational. To become effective, the Order had to be approved either by a majority of producers, feeders, and importers voting in the referendum or by voters who accounted for at least two-thirds of the production represented by all persons voting in the referendum. Of the 19,801 valid ballots cast in the February 6, 1996, referendum, 10,707 (54 percent) favored implementation of the Order and 9,094 (46 percent) opposed implementation of the Order.

AMS published the final Order (61 FR 19514) on May 2, 1996, to implement a national sheep and wool, promotion, research, education, and information program, designed to strengthen the position of sheep and sheep products in the marketplace, as provided for under the Act. The effective date of the Order was May 3, 1996, except that the collection and remittance sections of the Order—§ 1280.224–§ 1280.228—were scheduled to become effective on July 1, 1996. The final Rules and Regulations (61 FR 21053), which set forth the collection and remittance procedures to be used beginning July 1, 1996, and the Certification and Nomination procedures (61 FR 21049), which outline eligibility criteria and the nomination process used to obtain nominations for appointment to the National Sheep Promotion, Research, and Information Board which would administer the program, were both published on May 9, 1996.

After the referendum was held, however, the Department received voter complaints of alleged inconsistencies in the application of the referendum rules in conducting the referendum. The Department initiated a review of these allegations. Based on findings of the review which revealed that the referendum rules were applied inconsistently, the Department voided the results of the February 6, 1996, referendum, suspended the Order and the Certification and Nomination Regulations and postponed indefinitely the announced July 1, 1996, effective date of (1) the implementing Rules and Regulations, (2) the collection of assessments, and (3) the collection and remittance sections of the Order—§ 1280.224–§ 1280.228. The second referendum will be conducted under the final referendum rules published December 15, 1995 (60 FR 64297), in the Federal Register.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Office of Management and Budget (OMB) has approved the information collection requirements concerning the conduct of a referendum including ballots and other voting materials. The control number assigned to the information collection requirements by OMB is OMB 0581–0093. It is estimated that it will take an average of 6.5 minutes for each of the approximately 87,350 domestic sheep producers and sheep feeders and the approximately 9,000 importers of sheep and sheep products to cast a ballot.

Referendum Order

It is hereby directed that a referendum be conducted among eligible sheep producers, sheep feeders, and importers of sheep and sheep products to determine whether an Order will become effective if approved by those eligible persons voting in the referendum. In-person voting in the referendum will be conducted on October 1, 1996, by the county CES offices. Absentee ballots will be available at the county CES offices from August 26, 1996, through September 17, 1996. The representative period to establish voter eligibility will be the period from January 1, 1994, through December 31, 1994.

List of Subjects in 7 CFR Part 1280

Administrative practice and procedure, Advertising, Agricultural research, Marketing agreements, Sheep and sheep products, Reporting and recordkeeping requirements.

Authority: 7 U.S.C. 7101–7111.

Dated: July 3, 1996.
Lon Hatamiya,
Administrator.
[FR Doc. 96–17478 Filed 7–3–96; 3:48 pm]
BILLING CODE 3410–02–P

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Parts 207 and 208

[INS No. 1639–93]

RIN 1115–AD59

Procedures for Filing a Derivative Petition (Form I–730) for a Spouse and Unmarried Children of a Refugee/Asylee

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Proposed rule.

SUMMARY: This rule proposes to amend the Immigration and Naturalization Service (Service) regulations by providing procedures which must be followed by a refugee to bring his/her spouse and unmarried, minor child(ren) (derivatives) into the United States. This proposed rule is intended to respond to the family reunification needs of refugees by establishing an equitable and consistent following-to-join policy for refugees which parallels the current following-to-join procedures for asylees. This rule also proposes to amend asylum regulations by removing from the definition of qualifying relationship child(ren) born to or legally adopted by the principal alien and spouse after approval of the principal alien's asylum application.

DATES: Written comments must be submitted on or before September 9, 1996.

ADDRESSES: Please submit written comments, in triplicate, to the Policy Directives and Instructions Branch, Immigration and Naturalization Service, 425 I Street, NW., Room 5307, Washington, DC 20536, Attention: Public Comment Clerk. To ensure proper handling, please reference INS No. 1639–93 on your correspondence. Comments will be available for public inspection at this location by calling (202) 514–3048 to arrange an appointment.

FOR FURTHER INFORMATION CONTACT: Ramonia Law-Hill, Senior Adjudications Officer, Adjudications Division, Immigration and Naturalization Service, 425 I Street, NW., Room 3214, Washington, DC 20536, telephone (202) 514–5014.

SUPPLEMENTARY INFORMATION:

A. Background

The United States refugee program places strong emphasis on family reunification and assigns priority for interviews to those refugee applicants who have immediate family members already in the United States. This emphasis on reunifying families also extends to those refugees who have been resettled in the United States, but who remain separated from their spouse and/or child(ren). In such cases, refugees may file to have their spouse and/or child(ren) ''follow-to-join'' them in the United States. The following-to-join provisions for refugees is found in section 207(c)(2) of the Immigration and Nationality Act (Act).

To apply for such benefits, refugees file Form I–730, Refugee/Asylee Relative Petition, with the designated Service office. Such designation will be through separate action in the Federal Register. Spouses and unmarried, minor children (derivatives) who follow-to-join a refugee already in this country are admitted as refugees.

B. Need for Procedural Review and Revised Regulation

Over the past year, it has become apparent that existing Service procedures regarding following-to-join benefits for refugees is inadequate and has resulted in confusion for the general public. Regulations are necessary to clarify procedures and to establish an equitable and consistent following-to-join policy for refugees which parallels that found in the current following-to-join regulations for asylees, who are also eligible to file Form I–730.

In recent months the Service has received numerous telephone inquiries from members of Congress, the general public, voluntary agencies, and attorneys representing clients concerning the application of the following-to-join provisions found in section 207(c)(2) of the Act. Of primary concern has been the Service's requirement that the refugee's relationship to the spouse and/or child predates the date on which the refugee was granted refugee status. A Service memorandum issued on January 8, 1987, defined this date as the date of tentative approval, which has been interpreted by some as being the day of the refugee's interview. That interpretation, however, has not received Servicewide acceptance.

The Service's recent initiative to combine the Form I–730 with the revised Form I–130 (Petition for Alien Relative), revealed differing practices for processing following-to-join petitions filed by refugees and those filed by aslyees. It was, therefore, determined that rather than consolidate the forms, the Service needed to review and, if necessary, revise existing policies relating to refugees and asylees.

C. Following-to-Join Issue

In the absence of a time limit on the following-to-join regulations, individuals who entered the United States as conditional entrants in the late 1970s and refugees in the early 1980s are filing Form I–730 petitions for a spouse and/or child(ren). Following-to-join benefits are available to help refugees make the difficult transition to a new life with the support of their immediate family members. Forms I–730 filed ten or more years after admission no longer serve the purpose for which they were originally intended. Instead, they deplete limited refugee admission numbers and refugee resettlement monies needed for emerging refugee populations. The proposed regulations are intended to respond more fully to the family reunification needs of refugees, while establishing specific guidelines on the following-to-join process.

Current interpretations of the following-to-join benefits for refugees have created confusion for Service officers, attorneys, refugees, and the general public. While some interpret following-to-join eligibility based on the refugee's date of admission, current practice requires the relationship to exist prior to the tentative approval date of the principal's application for refugee status. The Service determined that the current interpretation of following-to-join for refugees is too restrictive since it requires a refugee to meet a heavier burden for establishing a relationship with his/her spouse and unmarried, minor child(ren), than is required by regulation for a spouse and unmarried minor child(ren) of a citizen or lawful permanent resident of the United States. To resolve this disparity, the Service is adopting a more generous interpretation of the point at which a qualifying relationship exists for following-to-join benefits. This rule proposes that the refugee's date of admission be used to determine following-to-join eligibility. A refugee will then be able to file a separate Form I–730 for his/her spouse and/or each individual child if the relationship predates the refugee's date of admission to the United States, rather than the date of interview. The Service believes this proposal reflects the intent of Congress to reunite refugees with their families. Further, it alleviates inconsistencies in determining eligibility as is currently encountered

because of the difficulty in determining the date of tentative approval.

Additionally, the Service has found that the benefit accorded asylees regarding children is too broad in that current asylum regulations extend following-to-join benefits to children born to, or adopted by, asylees at any point after the date of their approval. As a result, this rule will amend existing asylum regulations by requiring that, for purposes of filing a Form I–730, the asylee's relationship to a child exists on the date the asylee is granted asylum.

Only refugees who entered the United States as principal aliens will be eligible to file the Form I–730 for following-to-join benefits for a spouse and/or each individual unmarried, minor child under this proposed rule. Those individuals who have derived their refugee status from the principal alien will not be eligible to file Form I–730.

Past practice has allowed for the adjudication of Form I–730 filed by a son or daughter who claimed to be single in order to qualify as a member of a parent's refugee case, and who then petitioned for his/her spouse after arrival to the United States. As the proposed rule does not permit the filing of a Form I–730 by derivatives, this type of misrepresentation should be reduced. Only the spouse and unmarried, minor child(ren) of a refugee may benefit under the proposed following-to-join regulation.

Currently there is no established time to file for and receive following-to-join benefits, either for asylees or refugees. The proposed regulation will impose a 1-year time limit from the date of the principal's admission, within which a refugee or asylee must file a separate Form I–730 for each individual qualifying family member, unless it is clearly established that compelling circumstances preclude the timely filing of the application. Refugees or asylees who have resided in the United States for more than 1 year when this regulation becomes effective will be granted 1 year from the effective date of the final regulation in which to file Form I–730 for following-to-join benefits for their spouse and unmarried, minor child(ren). The Service may, however, waive the 1-year limit when it is determined that humanitarian reasons for extending the filing period exist. The 1-year limit refers only to the filing of the Form I–730. Such limit is not imposed on family members' travel to the United States, as the Service is aware of the impediments which may delay family members' travel for years following the refugee's arrival in the United States. The filing of the Form I–730 will serve to notify the Service of a refugee's or asylee's intent to have his/her spouse and/or child(ren) join him/her in the United States. The approval of the Form I–730 shall remain valid for the duration of the relationship to the refugee or asylee, and in the case of a child, while the child is under 21 years of age and unmarried, provided also that the principal's status has not been revoked.

The Service has established what it believes to be a reasonable time limit on the filing of the Form I–730. It is further believed that derivative benefits for spouses and children of refugees was intended for the purpose of reuniting families and to avoid lengthy delays due to visa quotas. Timely filings will expedite the reunification of refugee families and ensure the removal of spouses and children of refugees from a country subjecting them to persecution on the basis of that relationship. Thus, refugees must file following-to-join petitions within 1 year of the date of their admissions; asylees within 1 year of being granted asylum status.

While the rule proposes necessary bounds, such as adding eligibility requirements and establishing a filing period for following-to-join benefits, it is liberal in defining the point at which a qualifying relationship exists for this benefit. The proposed rule will clarify the Service's following-to-join policy for Service officers and the general public by standardizing refugee and asylee following-to-join procedures.

Regulatory Flexibility Act

The Commissioner of the Immigration and Naturalization Service, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and, by approving it, certifies that the rule will not have a significant economic impact on a substantial number of small entities because it is administrative in nature and merely imposes specific regulatory restraints, which parallel procedures currently found in asylum regulations.

Executive Order 12866

This rule is not considered by the Department of Justice, Immigration and Naturalization Service, to be a ''significant regulatory action'' under Executive Order 12866, section 3(f), Regulatory Planning and Review, and the Office of Management and Budget and waived its review process under section 6(a)(3)(A).

Executive Order 12612

The regulations proposed herein will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The Commissioner of the Immigration and Naturalization Service certifies that she has assessed this rule in light of the criteria in Executive Order 12606 and has determined that this regulation will enhance family well-being by establishing an equitable and consistent following-to-join policy for refugees which parallels the current following-to-join policy for asylees.

Paperwork Reduction Act

The information collection requirement (Form I–730) contained in this rule is being revised by the Immigration and Naturalization Service. In accordance with the Paperwork Reduction Act, the Service published a notice in the Federal Register on May 3, 1996, at 61 FR 19958, notifying the public of the revision to the Form I–730.

List of Subjects

8 CFR Part 207

Immigration, Refugees, Reporting and recordkeeping requirements.

8 CFR Part 208

Administrative practice and procedure, Aliens, Immigration, Reporting and recordkeeping requirements.

Accordingly, chapter I of title 8 of the Code of Federal Regulations is proposed to be amended as follows:

PART 207—ADMISSION OF REFUGEES

1. The authority citation for part 207 is revised to read as follows:

Authority: 8 U.S.C. 1103, 1157, 1159; 8 CFR Part 2.

§ 207.1 [Amended]

2. Section 207.1 is amended by removing paragraph (e).

§§ 207.7 and 207.8 [Redesignated as § 207.8 and § 207.9]

3. Sections 207.7 and 207.8 are redesignated as § 207.8 and 207.9 respectively.

4. A new § 207.7 is added to read as follows:

§ 207.7 Derivatives of refugees.

(a) *Eligibility.* A spouse, as defined in section 101(a)(35) of the Act, and/or child(ren), as defined in section 101(b)(1)(A), (B), (C), (D), or (E) of the

Act, may be granted refugee status if accompanying or following-to-join the principal alien. An accompanying derivative is a spouse or child of a refugee who is in the physical company of the principal refugee when he or she is admitted to the United States, or a spouse or child of a refugee who is admitted within 4 months of the principal refugee's admission. A following-to-join derivative, on the other hand, is a spouse or child of a refugee who seeks admission more than 4 months after the principal refugee's admission to the United States.

(b) *Ineligibility.* The following relatives of refugees are ineligible for accompanying or following-to-join benefits:

(1) A spouse or child who has previously been granted asylee or refugee status;

(2) An adopted child, if the adoption took place after the child became 16 years old, or if the child has not been in the legal custody and living with the parent(s) for at least 2 years;

(3) A stepchild, if the marriage that created this relationship took place after the child became 18 years old;

(4) A husband or wife if each/both were not physically present at the marriage ceremony, and the marriage was not consummated;

(5) A husband or wife if the U.S. Attorney General has determined that such alien has attempted or conspired to enter into a marriage for the purpose of evading immigration laws;

(6) A parent, sister, brother, grandparent, grandchild, nephew, niece, uncle, aunt, cousin or in-law.

(c) *Relationship.* The relationship of a spouse and child as defined in sections 101(a)(35) and 101(b)(1)(A), (B), (C), (D), or (E), respectively, of the Act, must have existed prior to the refugee's admission to the United States and must continue to exist at the time of filing for following-to-join benefits and admission to the United States. If the refugee proves that the refugee is the parent of a child who was born after the refugee's admission as a refugee, but who was *in utero* on the date of the refugee's admission as a refugee, the child shall be eligible to follow-to-join the refugee. The child's mother, if not the principal refugee shall not be eligible to follow-to-join the principal refugee unless the child's mother was the principal refugee's spouse on the date of the principal refugee's admission as a refugee.

(d) *Filing.* A refugee may request following-to-join benefits for his/her spouse and unmarried, minor child(ren) (whether the spouse and children are in or outside the United States) by filing a separate Form I–730, Refugee/Asylee Relative Petition, for each qualifying family member with the designated Service office. Persons who derive their refugee status from the principal applicant are not eligible to file Form I–730. The Form I–730 may only be filed by the principal applicant. Family members, such as unmarried sons and daughters who derived their refugee status, are not eligible to file the Form I–730 on behalf of their spouse and child(ren). A separate Form I–730 must be filed for each qualifying family member within 1 year of the refugee's admission to the United States, unless the Service determines that the filing period should be extended for humanitarian reasons. There is, however, no time limit imposed on family members' travel to the United States once the Form I–730 for following-to-join benefits has been approved, provided approval of the Form I–730 petition has not been subsequently revoked. There is no fee for filing this petition.

(e) *Evidence.* Documentary evidence consists of those documents which establish that the petitioner is a refugee, and evidence of the claimed relationship of the petitioner to the beneficiary. The burden of proof is on the petitioner to establish by a preponderance of the evidence that any person on whose behalf he/she is making a request under this section is an eligible spouse or unmarried, minor child. Evidence to establish the claimed relationship for a spouse or unmarried, minor child as set forth in 8 CFR part 204 must be submitted with the request for following-to-join benefits. Where possible this will consist of the documents specified in § 204.2(a)(1)(i)(B), (a)(1)(iii)(E), (a)(2), (d)(2), and (d)(5) of this chapter. In addition, a recent photograph of each derivative must accompany the Form I–730. Although the photograph need not meet Alien Documentation Identification and Telecommunication System (ADIT) specifications, it must clearly identify the derivative. The photograph will be made part of the derivative's immigration record for identification purposes.

(f) *Approvals.* (1) *Spouse or child in the United States.* When a spouse or child of a refugee is in the United States and the Form I–730 is approved, the Service will notify the refugee of such approval on Form I–797, Notice of Action. Employment will be authorized incident to status.

(2) *Spouse or child outside the United States.* When a spouse or child of a refugee is outside the United States and the Form I–730 is approved, the Service will notify the refugee of such approval on Form I–797. The approved Form I–730 will be sent by the Service to the Department of State for forwarding to the American Embassy or Consulate having jurisdiction over the area in which the refugee's spouse or child is located.

(3) *Benefits.* The approval of the Form I–730 shall remain valid for the duration of the relationship to the refugee and, in the case of a child, while the child is under 21 years of age and unmarried, provided also that the principal's status has not been revoked. However, the approved Form I–730 will cease to confer immigration benefits after it has been used by the beneficiary for admission to the United States as a derivative of a refugee. To demonstrate employment authorization, the Service will issue a Form I–94, Arrival-Departure Record, which also reflects the derivative's current status as a refugee, or the derivative may apply under § 274a.12(a) of this chapter, using Form I–765, Application for Employment Authorization, and a copy of the Form I–797.

(g) *Denials.* If the spouse or child of a refugee is found to be ineligible for derivative status, a written notice explaining the basis for denial shall be forwarded to the refugee. There shall be no appeal from this decision. However, the denial shall be without prejudice to the consideration of a new petition or motion to reopen the refugee and asylee relative petition proceedings, if the refugee establishes eligibility for the following-to-join benefits contained in this part.

PART 208—PROCEDURES FOR ASYLUM AND WITHHOLDING OF DEPORTATION

5. The authority citation for part 208 continues to read as follows:

Authority: 8 U.S.C. 1103, 1158, 1226, 1252, 1282; 31 U.S.C. 9701; 8 CFR part 2.

6. In § 208.21, paragraphs (b), (c), (d), and (f) are revised to read as follows:

§ 208.21 Admission of asylee's spouse and children.

* * * * *

(b) *Relationship.* The relationship of spouse and child as defined in sections 101(a)(35) and 101(b)(1) of the Act must have existed at the time the principal alien's asylum application was approved. If the asylee proves that the asylee is the parent of a child who was born after asylum was granted, but who was *in utero* on the date of the asylum grant, the child shall be eligible to follow-to-join the asylee. The child's mother, if not the principal asylee, shall

not be eligible to follow-to-join the principal asylee unless the child's mother was the principal asylee's spouse on the date of the principal asylee's grant as an asylee.

(c) *Spouse or child in the United States.* When a spouse or child of an alien granted asylum is in the United States, but was not included in the asylee's application, the asylee may request following-to-join benefits for his/her spouse or child by filing for each qualifying family member a separate Form I–730, Refugee/Asylee Relative Petition, and supporting evidence, with the designated Service office, regardless of the status of that spouse or child in the United States. The Form I–730 must also be accompanied by a recent, clear non-ADIT style photograph for each derivative. The photograph will be used for identification purposes and will be placed in the derivative's immigration record. Additionally, a separate Form I–730 must be filed by the asylee for each qualifying family member within 1 year of the date in which he/she was granted asylum status, unless it is determined by the Service that this period should be extended for humanitarian reasons. Upon approval of the Form I–730, the Service will notify the asylee of such approval on Form I–797 ''Notice of Action.'' Employment will be authorized incident to status. To demonstrate employment authorization, the Service will issue a Form I–94, Arrival-Departure Record, which also reflects the derivative's current status as an asylee, or the derivative may apply under § 274a.12(a) of this chapter, using Form I–765, Application for Employment Authorization, and a copy of the Form I–797. The approval of the Form I–730 shall remain valid for the duration of the relationship to the asylee and, in the case of a child, while the child is under 21 years of age and unmarried, provided also that the principal's status has not been revoked. However, the approved Form I–730 will cease to confer immigration benefits after it has been used by the beneficiary for admission to the United States as a derivative of an asylee.

(d) *Spouse or child outside the United States.* When a spouse or child of an alien granted asylum is outside the United States, the asylee may request following-to-join benefits for his/her spouse or child(ren) by filing a separate Form I–730 for each qualifying family member with the designated Service office, setting forth the full name, relationship, date and place of birth, and current location of each such person. The Form I–730 must be accompanied by a recent, clear non-ADIT style photograph for each derivative. A separate Form I–730 for each qualifying family member must be filed within 1 year of the date in which the asylee was granted asylum status, unless the Service determines that the filing period should be extended for humanitarian reasons. When the Form I–730 is approved, the Service will notify the asylee of such approval on Form I–797. The approved Form I–730 shall be forwarded by the Service to Department of State for delivery to the American Embassy or Consulate having jurisdiction over the area in which the asylee's spouse or child is located. The approval of the Form I–730 shall remain valid for the duration of the relationship to the asylee and, in the case of a child, while the child is under 21 years of age and unmarried, provided also that the principal's status has not been revoked. However, the approved Form I–730 will cease to confer immigration benefits after it has been used by the beneficiary for admission to the United States as a derivative of an asylee.

* * * * *

(f) *Burden of proof.* To establish the claimed relationship of spouse or child as defined in sections 101(a)(35) and 101(b)(1) of the Act, evidence must be submitted with the request as set forth in part 204 of this chapter. Where possible this will consist of the documents specified in § 204.2 (a)(1)(i)(B), (a)(1)(iii)(E), (a)(2), (d)(2) and (d)(5) of this chapter. The burden of proof is on the principal alien to establish by a preponderance of the evidence that any person on whose behalf he or she is making a request under this section is an eligible spouse or child.

* * * * *

Dated: May 7, 1996.

Doris Meissner,

Commissioner, Immigration and Naturalization Service.

[FR Doc. 96–17265 Filed 7–8–96; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. 96–027–1]

Change in Disease Status of the Czech Republic and Italy Because of Rinderpest and Foot-and-Mouth Disease

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to declare the Czech Republic and Italy free of rinderpest and foot-and-mouth disease and to add these two countries to the list of countries that, although declared free of rinderpest and foot-and-mouth disease, are subject to special restrictions on the importation of their meat and other animal products into the United States. This proposed rule would remove the prohibition on the importation into the United States, from the Czech Republic and Italy, of live ruminants and fresh, chilled, and frozen meat from ruminants and would relieve restrictions on the importation of milk and milk products from ruminants from these two countries. However, because the Czech Republic and Italy are not declared to be free of certain diseases of swine, including hog cholera and swine vesicular disease, the importation from these countries of swine and fresh, chilled, and frozen meat from swine would continue to be restricted.

DATES: Consideration will be given only to comments received on or before September 9, 1996.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 96–027–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. 96–027–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690–2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Dr. John Cougill, Staff Veterinarian, Products Program, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737–1228, (301) 734–3399.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 94 (referred to below as the regulations) govern the importation into the United States of specified animals and animal products in order to prevent the introduction into the United States of various diseases, including rinderpest, foot-and-mouth disease (FMD), bovine spongiform encephalopathy, African swine fever, hog cholera, and swine vesicular disease. These are dangerous and destructive communicable diseases of ruminants and swine.

Section 94.1(a)(1) of the regulations provides that rinderpest or FMD exists in all countries of the world except those listed in § 94.1(a)(2), which have been declared to be free of these diseases. We will consider declaring a country to be free of rinderpest and FMD if, among other things, there have been no cases of these diseases reported there for at least the previous 1-year period and no vaccinations for rinderpest or FMD have been administered to swine or ruminants in that country for at least the previous 1-year period.

Rinderpest has not existed in the Czech Republic since 1881, and vaccination for rinderpest has never occurred in the Czech Republic. The last diagnosed case of FMD in the Czech Republic occurred in 1974, and the government of the Czech Republic has prohibited vaccinations for FMD since 1991. The last case of rinderpest in Italy occurred in 1949, and Italy has never used vaccinations for rinderpest. The last outbreak of FMD in Italy occurred in 1993, and vaccinations for FMD in that country ceased in 1991.

The Czech Republic and Italy have individually applied to the U.S. Department of Agriculture (USDA) to be recognized as free of rinderpest and FMD. The Animal and Plant Health Inspection Service (APHIS) has reviewed the documentation submitted by the governments of the Czech Republic and Italy in support of their requests. The documentation supplied separately by the Czech Republic and Italy included, among other things, information about the capability of each country's veterinary services, laboratory and diagnostic procedures, vaccination practices, and the administration of laws and regulations to ensure against the introduction into the Czech Republic and Italy of rinderpest and FMD through the importation of live animals, meats, and animal products.

Based on the information discussed above, we believe that the Czech Republic and Italy qualify to be designated as free of rinderpest and FMD. Therefore, we are proposing to add the Czech Republic and Italy to the list in § 94.1(a)(2) of countries declared free of rinderpest and FMD. This action would remove the prohibition on the importation, from the Czech Republic and Italy, of live ruminants and fresh, chilled, or frozen meat from ruminants and would relieve restrictions on the importation, from these two countries, of milk and milk products from ruminants. The importation, from the Czech Republic and Italy, of live swine and fresh, chilled, or frozen meat from swine would continue to be restricted under 9 CFR part 94 because these countries have not been declared free of hog cholera and swine vesicular disease, and also because Italy has not been declared free of African swine fever.

Special Restrictions

We also propose to add the Czech Republic and Italy to the list in § 94.11(a) of countries declared free of rinderpest and FMD that are subject to special restrictions on the importation of their meat and other animal products into the United States. The countries listed in § 94.11(a) are subject to these special restrictions because they: (1) Supplement their national meat supply by importing fresh, chilled, or frozen meat of ruminants or swine from countries that are designated in § 94.1(a) as infected with rinderpest or FMD; or (2) have a common land border with countries designated as infected with rinderpest or FMD; or (3) import ruminants or swine from countries designated as infected with rinderpest or FMD under conditions less restrictive than would be acceptable for importation into the United States.

Both the Czech Republic and Italy supplement their national meat supplies by the importation of fresh, chilled, and frozen meat of ruminants and swine from countries designated in § 94.1(a)(1) as countries in which rinderpest or FMD exists. In addition, the Czech Republic shares a common land border with Russia, and Italy shares a common land border with Yugoslavia. Both Russia and Yugoslavia are designated in § 94.1(a)(1) as being countries in which rinderpest or FMD exists. Furthermore, both Italy, as a member of the European Union, and the Czech Republic import live ruminants and swine from countries not recognized as being free of FMD under conditions less restrictive than would be acceptable for importation into the United States. As a result, even though we propose to designate the Czech Republic and Italy as being free of rinderpest and FMD, the meat and other animal products produced in these countries may be commingled with the fresh, chilled, or frozen meat of animals from a country in which rinderpest and FMD exists, resulting in an undue risk of introducing rinderpest or FMD into the United States.

Therefore, we are proposing that meat and other animal products of ruminants and swine and the ship stores, airplane meals, and baggage containing these meat or animal products imported into the United States from the Czech Republic and Italy be subject to the restrictions specified in § 94.11 of the regulations, in addition to other applicable requirements of the USDA's Food Safety and Inspection Service at 9 CFR Chapter III. Section 94.11 generally requires that the meat and other animal products of ruminants and swine be: (1) Prepared in an inspected establishment that is eligible to have its products imported into the United States under the Federal Meat Inspection Act; and (2) accompanied by an additional certificate, issued by a full-time salaried veterinary official of the national government of the exporting country, assuring that the meat or other animal products have not been commingled with or exposed to meat or other animal products originating in, imported from, or transported through a country infected with rinderpest or FMD.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review process required by Executive Order 12866.

This proposed rule would alter the restrictions placed upon imports of live ruminants and meat, meat products, and dairy products derived from ruminants from the Czech Republic and Italy. The regulations in 9 CFR part 94 describe prohibited and restricted importations due to rinderpest, FMD, and other animal diseases. APHIS believes that the Czech Republic and Italy meet the criteria for being recognized as free of rinderpest and FMD. However, because the Czech Republic and Italy share land borders and maintain trading relationships with FMD-affected countries, imports into the United States of live ruminants and meat, meat products, and dairy products derived from ruminants from the Czech Republic and Italy would still be restricted under this proposed rule. The proposed rule would not relieve any restrictions imposed on the importation of swine and pork products because the Czech Republic and Italy are still considered to be affected with hog cholera and swine vesicular disease, and Italy is also considered to be affected with African swine fever.

We anticipate that the quantity of imports of live cattle, sheep, and goats from the Czech Republic and Italy into the United States would be minimally affected by the proposed rule. Live cattle imports would still be restricted due to the trade practices of the Czech Republic and Italy and the fact that these countries share land borders with FMD-affected countries. In addition, the cattle industries in the Czech Republic and Italy are small relative to the enormous domestic market. Cattle

inventories for 1994 were estimated to be 2.5 million head for the Czech Republic, 7.5 million head for Italy, and over 100 million head for the United States. Also, of the 2.5 million cattle and calves imported into the United States in 1994, more than 99 percent were from Canada and Mexico.

The population of sheep and goats in the Czech Republic is also very small relative to that of the United States (less than 2.5 percent of the size of the U.S. population in 1993). Italy has a sheep population that is slightly higher than that of the United States (11.7 million head in Italy and 10.9 million head in the United States in 1993). However, Italy is a strong net importer of sheep and goats (190,556 head imported and only 1,450 exported in 1993), while the United States is a strong net exporter of sheep and goats (28,420 head imported and 894,100 head exported in 1993). Of the few sheep that the United States does import, more than 99 percent are from Canada and Mexico.

The Czech Republic exports few live ruminants to the United States. In 1994, less than 0.0001 percent of the total value of total U.S. imports of live ruminants were from the Czech Republic. Italy exported no live ruminants to the United States in 1994. In fact, the United States did not import any cattle or sheep from the European Union in 1994. Neither Eastern nor Western Europe are usual sources of live ruminants for the United States, and any increase in ruminant importations from the Czech Republic or Italy prompted by this proposed rule would likely be negligible. Therefore, the impact on small domestic farmers of cattle, sheep, and goats would likely be minimal.

Czech production of beef, veal, mutton, and goat meat in 1994 was about 2 percent of the size of U.S. production. Italian production of beef, veal, mutton, and goat meat in 1994 was about 1.2 million metric tons, or about 11 percent of the U.S. production of 11.3 million metric tons. The United States imports very little in the way of ruminant meat and ruminant meat products from Eastern or Western Europe in general. Moreover, more than 88 percent of the imports of ruminant meat and ruminant meat products that come into the United States are from Australia, Canada, and New Zealand. It is unlikely that either the Czech Republic or Italy would be willing or able to redirect a significant portion of its ruminant meat production for export exclusively to the United States as a result of the proposed rule, given that restrictions would remain in place for imports into the United States. Even if the Czech Republic were able to redirect its entire production of these products for export to the United States, this production was only one-fifth the size of total U.S. imports of these products in 1994. Moreover, Italy is a significant net importer of beef, veal, mutton, and other products such as offal and meat extracts. Therefore, any effect of the proposed rule on domestic prices or supplies would likely be negligible, and thus the impact on small domestic producers would be minimal.

We also anticipate that the effect of the proposed rule on the importation of dairy products from the Czech Republic and Italy would be minimal. Czech production of dairy products is small relative to that of the United States. In 1993, Czech dairy product production was about 5 percent of the value of U.S. production. The United States imports little in the way of dairy products from the Czech Republic or from Eastern Europe in general. In 1994, U.S. imports of dairy products were valued at $963.4 million; of this total, less than 5 percent originated in Eastern Europe and less than 0.1 percent in the Czech Republic. The Czech Republic is a significant producer and exporter of butter. However, butter is already exempt from the provisions of 9 CFR part 94 and thus would be unaffected by the proposed rule. For dairy products in general, Italy is a significant net importer and not likely to be willing or able to redirect a significant portion of its production exclusively to the United States, which is a significant net exporter. Italy's major dairy export to the United States is cheese. Because solid cheeses are already exempt from the provisions of 9 CFR part 94, there is no reason to believe that imports of cheese would increase significantly due to this proposal. For these reasons and given the fact that restrictions will remain in place, it is unlikely that the proposed rule would significantly alter imports of dairy products into the United States. Therefore, the impact on small domestic dairy producers should be minimal.

Any effects of the proposed rule on importers of embryos, semen, other genetic material, or breeding animals would also likely be minimal. We anticipate that, if the proposal is made final for the Czech Republic and Italy, there could be an initial increase in the volume of these products flowing into the United States to diversify the genetic composition of domestic cattle. (In particular, there has been a great deal of interest expressed in obtaining genetic material of beef cattle from Italy.) However, any temporary increase in volume would most likely be small relative to total U.S. imports of these products. The United States is a net exporter of both bovine semen and cattle embryos. In 1994, the value of U.S. bovine semen and cattle embryo imports was $4.3 million and $266,000, respectively, while U.S. exports of bovine semen and cattle embryos were valued at $7.9 million and $6.4 million, respectively. Given this trade balance and the size differences between the U.S. and Czech and Italian cattle industries, the amount imported of each type of genetic material would be minimal and have a minimal impact on small domestic cattle producers.

In conclusion, declaring the Czech Republic and Italy free of rinderpest and FMD would likely have a negligible impact on domestic small entities. Imports from the Czech Republic and Italy of ruminants and ruminant products would continue to be restricted. In addition, the U.S. markets for these products are large relative to the Czech and Italian markets, and Italy is a net importer of most of these products. Under these conditions, it is unlikely that either the Czech Republic or Italy would be willing or able to redirect a significant portion of the production of these products exclusively to the United States.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been approved by the Office of Management and Budget (OMB). The assigned OMB control number is 0579–0015.

List of Subjects in 9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

Accordingly, 9 CFR part 94 would be amended as follows:

PART 94–RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), VELOGENIC VISCEROTROPIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, HOG CHOLERA, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

1. The authority citation for part 94 would continue to read as follows:

Authority: 7 U.S.C. 147a, 150ee, 161, 162, and 450; 19 U.S.C. 1306; 21 U.S.C. 111, 114a, 134a, 134b, 134c, 134f, 136, and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.2(d).

§ 94.1 [Amended]

2. In § 94.1, paragraph (a)(2) would be amended by adding the words ''Czech Republic,'' immediately after the words ''Costa Rica,'' and by adding the word ''Italy,'' immediately after the word ''Ireland,''.

§ 94.11 [Amended]

3. In § 94.11, the first sentence in paragraph (a) would be amended by adding the words ''Czech Republic,'' immediately after the word ''Chile,'' and by adding the word ''Italy,'' immediately after the word ''Hungary,''.

Done in Washington, DC, this 2nd day of July 1996.

Terry L. Medley,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 96–17440 Filed 7–8–96; 8:45 am]

BILLING CODE 3410–34–P

Food Safety and Inspection Service

9 CFR Parts 301, 318, 320, and 381

[Docket No. 95–033E]

RIN 0583–AB94

Performance Standards for the Production of Certain Cooked Meat and Poultry Products—Reopening of Comment Period

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Reopening of comment period.

SUMMARY: The Food Safety and Inspection Service (FSIS) is extending the comment period for the proposed rule, ''Performance Standards for the Production of Certain Cooked Meat and Poultry Products'' (61 FR 19564, May 2, 1996) for 60 days.

DATES: Comments must be received on or before September 9, 1996.

ADDRESSES: Submit one original and two copies of written comments to: FSIS Docket Clerk, DOCKET #95–033P, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 4352, 1400 Independence Ave., SW, Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT: Patricia F. Stolfa, Associate Deputy Administrator, Science and Technology; (202) 205–0699.

Done in Washington, DC, July 2, 1996.

Michael R. Taylor,

Acting Under Secretary for Food Safety.

[FR Doc. 96–17360 Filed 7–8–96; 8:45 am]

BILLING CODE 3410–DM–P

9 CFR Parts 304, 308, and 381

[Docket No. 95–032E]

RIN 0583–AB93

Elimination of Prior Approval Requirements for Establishment Drawings and Specifications, Equipment, and Certain Partial Quality Control Programs—Reopening of Comment Period

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Reopening of comment period.

SUMMARY: The Food Safety and Inspection Service (FSIS) is extending the comment period for the proposed rule, ''Elimination of Prior Approval Requirements for Establishment Drawings and Specifications, Equipment, and Certain Partial Quality Control Programs'' (61 FR 19578, May 2, 1996) for 60 days.

DATES: Comments must be received on or before September 9, 1996.

ADDRESSES: Submit one original and two copies of written comments to: FSIS Docket Clerk, DOCKET #95–032P, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 4352, 1400 Independence Ave., SW, Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT: Patricia F. Stolfa, Associate Deputy Administrator, Science and Technology; (202) 205–0699.

Done in Washington, DC, July 2, 1996.

Michael R. Taylor,

Acting Under Secretary for Food Safety.

[FR Doc. 96–17361 Filed 7–8–96; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF ENERGY

10 CFR Part 1021

RIN 1901–AA67

National Environmental Policy Act Implementing Procedures

AGENCY: Department of Energy.

ACTION: Proposed rule; limited reopening of the comment period.

SUMMARY: This Notice announces a limited reopening of the comment period with respect to the proposed rule on implementation of the National Environmental Policy Act (NEPA). DOE has decided to solicit further input on certain proposed amendments that pertain primarily to Federal power marketing activities. In a related document published elsewhere in this issue, DOE is publishing final amendments to 10 CFR 1021 not affected by this limited reopening of the comment period.

DATES: The limited reopening of the comment period will end August 8, 1996. Comments must be received by that date to ensure consideration. Late comments will be considered to the extent practicable.

ADDRESSES: Comments should be addressed to Carol M. Borgstrom, Director, Office of NEPA Policy and Assistance, EH–42, U.S. Department of Energy, 1000 Independence Avenue, S.W., Washington, D.C. 20585–0119. Comments may be hand-delivered to room 3E–080 at the Forrestal Building on workdays between the hours of 8:00 a.m. and 4:30 p.m. Comments may also be sent by facsimile to (202) 586–7031 or by electronic mail to the following Internet address: neparule@spok.eh.doe.gov. All comments will be available for public inspection at the U.S. Department of Energy Freedom of Information Reading room, 1E–110 Forrestal Building, 1000 Independence Avenue S.W., Washington, D.C. 20585–0119, phone (202) 586–6020.

FOR FURTHER INFORMATION CONTACT: John Pulliam, Office of NEPA Policy and Assistance, at the above address, or telephone (202) 586–4600 or leave a message at (800) 472–2756.

SUPPLEMENTARY INFORMATION: On February 20, 1996 (61 FR 6414), the Department of Energy (DOE) published a Notice of Proposed Rulemaking to amend its implementing procedures under the National Environmental Policy Act (NEPA) (10 CFR part 1021). Publication of the proposed rulemaking began a 45-day public comment period that originally ended on April 5, 1996.

In response to public requests, the comment period was reopened on April 19 and extended until May 10, 1996. A public hearing was also held in Washington, D.C. on May 6, 1996. DOE has decided to solicit further input, especially from state and Federal agencies that have responsibility for environmental review of comparable non-Federal utility projects in the Pacific Northwest, on the following proposed amendments to Subpart D, typical Classes of Action primarily affecting power marketing activities: B4.1, Contracts/marketing plans/policies for excess electric power; B4.2, Export of electric energy; B4.3, Electric power marketing rate changes; B4.6, Additions/modifications to electric power transmission facilities within previously developed area; B4.10, Deactivation, dismantling and removal of electric powerlines and substations; B4.11, Construction or modification of electric power substations; B4.12, Construction of electric powerlines (generally less than 10 miles in length), not integrating major new sources; B4.13, Reconstruction and minor relocation of existing electric powerlines (generally less than 20 miles in length); C4, Upgrading and constructing electric powerlines; C7, Allocation of electric power, no major new generation resource/major changes in operation of generation resources/major new loads; and D7, Allocation of electric power, major new generation resources/major changes in operation of generation resources/major loads. DOE is reopening the comment period on these proposed amendments only. The final rule on all of the proposed amendments other than those that pertain to power marketing activities is being published separately.

In response to a request, DOE is providing further clarification of the rationale for two of the proposed amendments: B4.1, Contracts/marketing plans/policies for excess electric power, and B4.3, Electric power marketing rate changes. For ease of comparison, the current B4.1 and B4.3 as they now appear in the DOE NEPA regulations (57 FR 15122, 1992) are reprinted below, followed by the amended language from the February 1996 proposed rule, and the clarified rationale for the amendment.

Current B4.1

Establishment and implementation of short-term contracts, marketing plans, policies, annual operating plans, allocation plans or acquisition of excess power, the terms of any of which do not exceed five years and would not cause changes in the normal operating limits of generating projects, and if transmission would occur over existing transmission systems.

Proposed B4.1

Establishment and implementation of contracts, marketing plans, policies, allocation plans or acquisition of excess electric power that does not involve: (1) The integration of a new generation resource, (2) physical changes in the transmission system beyond the previously developed facility area, unless the changes are themselves categorically excluded, or (3) changes in the normal operating limits of generation resources.

Rationale for Amendment

The existing five-year term limit was proposed for elimination from this categorical exclusion because past experience has demonstrated that the mere length of a contract, policy, or plan does not have the potential for environmental impacts. Rather, the development or integration of new generating resources, changes in the operation of existing generation resources, or construction of transmission facilities, are the types of activities that have shown the potential for environmental impacts. By not allowing these changes in generation, operation or transmission, the proposed categorical exclusion would ensure that only those actions which have no potential for environmental impact would be categorically excluded. Those contracts, plans, and policies that do not satisfy the proposed criteria would require further NEPA analysis to ascertain the associated environmental impacts.

Current B4.3

Changes in rates for electric power, power transmission, and other products or services provided by a Power Marketing Administration that are based on a change in revenue requirements that does not exceed the change in the overall price level in the economy (inflation), as measured by the GNP fixed weight price index published by the Department of Commerce, during the period since the last rate adjustment for that product or service or, if the rate change does exceed the change in the GNP fixed weight price index, the rate change would have no potential for affecting the operation of power generation resources.

Proposed B4.3

Changes in rates for electric power, power transmission, and other products or services provided by a Power Marketing Administration that are based on a change in revenue requirements if the operations of generation projects would remain within the normal operating limits.

Rationale for Amendment

The proposed change would eliminate the existing restriction that, in order to be categorically excluded, a proposed rate change must not exceed the rate of inflation, a condition that DOE has found is not relevant to the action's potential for environmental impacts. Any environmental impacts resulting from rate changes would be caused only if the rate change involved associated changes in generation resources. This categorical exclusion would only apply to those rate changes that would not affect the operation of generation projects. Those rate changes that could affect the operation of generation projects would require further NEPA analysis.

Issued in Washington, D.C., June 28, 1996.

Tara O'Toole,

Assistant Secretary, Environment, Safety and Health.

[FR Doc. 96–17286 Filed 7–8–96; 8:45 am]

BILLING CODE 6450–01–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 96–ASW–13]

Proposed Revision of Class E Airspace; Russellville, AR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to revise the Class E airspace extending upward from 700 feet above ground level (AGL) at Russellville, AR. A new Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) to Runway (RWY) 25 at Russellville Municipal Airport has made this proposal necessary. The intended effect of this proposal is to provide adequate controlled airspace for aircraft executing the GPS SIAP to RWY 25 at Russellville Municipal Airport, Russellville, AR.

DATES: Comments must be received on or before September 6, 1996.

ADDRESSES: Send comments on the proposal in triplicate to Manager, Operations Branch, Air Traffic Division, Federal Aviation Administration, Southwest Region, Docket No. 96–ASW–13, Fort Worth, TX 76193–0530. The official docket may be examined in

the Office of the Assistant Chief Counsel, Federal Aviation Administration, Southwest Region, 2601 Meacham Boulevard, Fort Worth, TX, between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the Operations Branch, Air Traffic Division, Federal Aviation Administration, Southwest Region, 2601 Meacham Boulevard, Fort Worth, TX.

FOR FURTHER INFORMATION CONTACT: Donald J. Day, Operations Branch, Air Traffic Division, Federal Aviation Administration, Southwest Region, Fort Worth, TX 76193–0530; telephone: (817) 222–5593.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed under the caption **ADDRESSES.** Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit, with those comments, a self-addressed, stamped, postcard containing the following statement: ''Comments to Airspace Docket No. 96–ASW–13.'' The postcard will be date and time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in the light of comments received. All comments submitted will be available for examination in the Office of the Assistant Chief Counsel, Federal Aviation Administration, Southwest Region, 2601 Meacham Boulevard, Fort Worth, TX, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Operations Branch, Air Traffic Division, Federal Aviation Administration, Southwest Region, Fort Worth, TX 76193–0530. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A that describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to revise the Class E airspace, controlled airspace extending upward from 700 feet AGL, at Russellville Municipal Airport, Russellville, AR. A new GPS SIAP to RWY 25 has made this proposal necessary. The intended effect of this proposal is to provide adequate Class E airspace for aircraft executing the GPS SIAP to RWY 25 at Russellville Municipal Airport, Russellville, AR.

The coordinates for this airspace docket are based on North American Datum 83. Designated Class E airspace areas extending upward from 700 feet or more above ground level are published in Paragraph 6005 of FAA Order 7400.9C, dated August 17, 1995, and effective September 16, 1995, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations that need frequent and routine amendments to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedure (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9C, *Airspace Designations and Reporting Points,* dated August 17, 1995, and effective September 16, 1995, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ASW AR E5 Russellville, AR [Revised]

Russellville, Russellville Municipal Airport, AR
(lat. 35°15′33″N., long. 93°05′38″W.)
Russellville NDB
(lat. 35°15′26″N., long. 93°05′40″W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Russellville Municipal Airport, and within 2.4 miles each side of the 184° bearing from the Russellville NDB extending from the 6.4-mile radius to 6.6 miles south of the airport, and within 4 miles each side of the 075° bearing from the airport extending from the 6.4-mile radius to 18 miles northeast of the airport, excluding that airspace which overlies the Morrilton, AR, Class E airspace area.

* * * * *

Issued in Fort Worth, TX on June 17, 1996.

Albert L. Viselli,

Acting Manager, Air Traffic Division, Southwest Region.

[FR Doc. 96–17418 Filed 7–8–96; 8:45 am]

BILLING CODE 4910–13–M

FEDERAL TRADE COMMISSION

16 CFR Part 303

Rules and Regulations Under the Textile Fiber Products Identification Act

AGENCY: Federal Trade Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: On October 30, 1992. Teijin Limited (''Teijin'') filed an application with the Federal Trade Commission (''Commission'') requesting the establishment of a new generic fiber name and definition. The application was filed pursuant to Rule 8 of the Rules and Regulations Under the Textile Fiber Products Identification Act (the ''Textile Act''—15 U.S.C. 70; implementing regulations at 16 CFR part 303). The

application maintains that its new fiber, ''manufactured from poly tetramethylene ether/poly butylene glycol terephthalate copolymer,'' has a unique chemical composition and distinctive physical characteristics such that it cannot be identified by any of the generic names already established by the Commission in Rule 7 (16 CFR 303.7). The application also states that Teijin intends to market the fiber commercially, and subsequent information from the applicant states that the fiber is now being used in the U.S. Teijin recommends that the new fiber be given one of the following generic names, in descending order of preference: (1) ''Polyetherester,'' (2) ''Elastoester,'' or (3) ''Estelast.'' The Teijin application includes a proposed definition for the new fiber.

The Commission now solicits comments as to whether Rule 7 should be amended to include a new generic name and definition covering Teijin's fiber.

DATES: Written comments will be accepted through September 9, 1996.

ADDRESSES: Submit written comments and other submissions to: Secretary, Federal Trade Commission, Room H–159, Sixth & Pennsylvania Avenue, N.W., Washington, D.C. 20580. Submissions should be marked: ''Rule 7 Under the Textile Act—Comment.''

FOR FURTHER INFORMATION CONTACT: Bret S. Smart, Program Advisor, Los Angeles Regional Office, Federal Trade Commission, 11000 Wilshire Boulevard, #13209, Los Angeles, CA 90024, (310) 235–4040.

SUPPLEMENTARY INFORMATION:

I. Background

Rule 6 (16 CFR 303.6) of the Rules and Regulations under the Textile Fiber Products Identification Act requires manufacturers to use the generic names of the fibers contained in their textile fiber products in making required disclosures of the fiber content of the products. Rule 7 (16 CFR 303.7) sets forth the generic names and definitions that the Commission has established or synthetic fibers. Rule 8 (16 CFR 303.8) sets forth the procedures for establishing new generic names.

Teijin submitted its initial application in this matter to the Commission on October 30, 1992, and subsequently submitted additional information. The application and related materials have been placed on the rulemaking record. After an initial analysis, the Commission, on December 29, 1992, issued the designation ''TL 0001'' for temporary use in identifying the Teijin fiber until a final determination can be made as to the merits of the application for a new generic name.

II. Chemical Composition, Physical and Chemical Properties

In its application, Teijin describes the fiber, its composition, and its physical and chemical properties, as follows:

The general formula of the chemical composition of poly tetramethylene ether/poly butylene glycol terephthalate copolymer, $-[(CH_2CH_2CH_2CH_2O)m]-(COC_6H_4COOCH_2CH_2CH_2CH_2O)n-$, consists of:

Poly tetramethylene ether $(CH_2CH_2CH_2CH_2O)m$: 60% by weight

Poly butylene glycol terephthalate $(COC_6H_4COOCH_2CH_2CH_2CH_2O)n$: 40% by weight

* * * * *

Assuming that poly(tetramethylene ether) glycol is considered a part of glycol components, then Applicant's fiber is somewhat similar to polyester. Nonetheless, Applicant's fiber is not ''composed of at least 85% by weight of an ester of a substituted aromatic carboxylic acid'' since poly tetramethylene ether is only 60%. Thus Applicant's fiber manufactured from poly tetramethylene ether/poly butylene glycol terephthalate copolymer does not fall under the Commission's definition of polyester fiber found in 16 CFR 303.7(c).

* * * * *

The physical and chemical characteristics of Applicant's fiber. . .are distinctively different from the characteristics of those fibers identified by generic names listed in 16 CFR 303.7.

The physical properties of Applicant's fiber are shown in [the following Table:]

	Applicant's fiber	Polyester fiber	Spandex fiber
Tenacity (g/de)	1.0	3.0–5.0	0.6–1.2
Elongation (%)	650	20–40	450–800
Elastic recovery (%) 200% extension	78	Break	90

As shown in the table, physical properties of Applicant's fiber are quite different from those of polyester but similar to those of the spandex fiber.

* * * * *

Applicant provides additional information, specifically technical data, which may be pertinent to this application. Typical properties of Applicant's fiber manufactured from poly tetramethylene ether/poly butylene glycol terephthalate copolymer include:

1. Physical Properties

Melting point	180–210 C
Specific gravity	1.1–1.2
Tenacity	1.0 g/de
Elongation	650%
Elastic recovery	78%
Boiling water shrinkage	14%

2. Resistance to Chemicals

Solubility at room temperature	
70% H_2SO_4	Insoluble for 3 minutes.
20% HCL	Do.
Conc. HNO_3	Do.
Acetic Acid	Do.
5% NaOH	Do.
Acetone	Do.
Toluene	Do.
Ethyl acetate	Do.
Methyl alcohol	Do.
Chloroform	Soluble.
m–Cresol	Do.
Solubility at boiling temperature	
Dioxane	Soluble.
Xylene	Do.
Nitrobenzene	Do.
Chlorobenzene	Do.
Dimethylformamide	Do.

Additionally, information submitted by Teijin indicates that, relative to spandex, REXE has the ability to withstand high temperatures when wet. This is particularly important with respect to dyeing. Teijin further states that REXE's tolerance of high temperature will allow the development of elastic fabrics with many of the properties of polyester. For example, fabrics made of REXE and polyester should have excellent washability. Finally, fabrics made of REXE and polyester are, according to Teijin, less discolored or adversely affected by chlorine than, for example, swimming suits made of nylon and spandex.

III. Suggested Generic Names

Applicant suggests the following generic names, in descending order of preference, for its new fiber:

1. ''Polyetherester''
2. ''Elastoester''

3. ''Estelast''

IV. Proposed Definition

The Commission proposes the following definition for Teijin's new fiber:

A manufactured fiber in which the fiber-forming substance is a long-chain synthetic polymer composed of at least 50% by weight of aliphatic polyether and at least 35% by weight of polyester, as defined in 16 CFR 303.7(c).

V. Invitation to Comment

The Commission is soliciting comment on Teijin's application generally, but is especially interested in comments on whether the application meets the following criteria, which the Commission has identified as grounds for granting applications for new generic names:

[T]he Commission, in the interest of elucidating the grounds on which it has based this decision and shall base future decisions as to the grant of generic names for textile fibers, sets out the following criteria for grant of such generic names.

1. The fiber for which a generic name is requested must have a chemical composition radically different from other fibers, and that distinctive chemical composition must result in distinctive physical properties of significance to the general public.

2. The fiber must be in active commercial use or such use must be immediately foreseen.

3. The grant of the generic name must be of importance to the consuming public at large, rather than to a small group of knowledgeable professionals such as purchasing officers for large Government agencies.

The Commission believes it is in the public interest to prevent the proliferation of generic names, and will adhere to a stringent application of the above-mentioned criteria in consideration of any future applications for generic names and in a systematic review of any generic names previously granted which no longer meet these criteria.

* * * * *

In addition, [the Commission] notes that where appropriate, in considering applications for new generic names for fibers that are of the same general chemical composition as those for which a generic name already has been established, rather than of a chemical composition that is radically different, but that have distinctive properties of importance to the general public as a result of a new method of manufacture of their substantially differentiated physical characteristics, such as their fiber structure, it may allow such fiber to be designated in required information disclosures by either its generic name, or alternatively, by its ''subclass'' name. The Commission will consider this disposition when the distinctive feature or features of the subclass fiber make it suitable for uses for which other fibers under the established generic name would not be suited or would be significantly less well suited. 60 FR 62352, 62353 (Dec. 6, 1995) (reaffirming and clarifying criteria first announced at 38 FR 34114 (Nov. 12, 1973)).

The Commission additionally requests comments on the suggested names and proposed definition, set out above.

Before deciding whether to amend Rule 7, the Commission will consider any written comments submitted to the Secretary of the Commission within the above-mentioned comment period. Comments that are submitted will be available for public inspection, in accordance with the Freedom of Information Act, 5 U.S.C. 552, and Commission Regulation, 16 CFR 4, on normal business days between the hours of 8:30 a.m. and 5:00 p.m. at the Public Reference Room, Room 130, Federal Trade Commission, 6th & Pennsylvania Avenue, N.W., Washington, D.C. 20580.

VI. Regulatory Flexibility Act

The provisions of the Regulatory Flexibility Act relating to an initial regulatory analysis (5 U.S.C. 603–604) are not applicable to this proposal because the Commission believes that the amendment, if promulgated, will not have a significant economic impact on a substantial number of small entities. The Commission has tentatively reached this conclusion with respect to the proposed amendment because the amendment would impose no additional obligations, penalties, or costs. The amendment would simply allow covered companies to use a new generic name for a new fiber that may not appropriately fit within current generic names and definitions. The amendment would impose no additional labeling requirements.

To ensure, however, that no substantial economic impact is being overlooked, public comment is requested on the effect of the proposed amendment on costs, profits, and competitiveness of, and employment in small entities. Subsequent to the receipt of public comments, the Commission will decide whether the preparation of a final regulatory flexibility analysis is warranted. Accordingly, based on available information, the Commission hereby certifies, pursuant to the Regulatory Flexibility Act (5 U.S.C. 605(b)), that the proposed amendment, if promulgated, would not have a significant economic impact on a substantial number of small entities.

VII. Paperwork Reduction Act

This proposed amendment does not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 109 Stat. 163) and its implementing regulations (5 CFR part 1320).

The collection of information imposed by the procedures for establishing generic names (Rule 8, 16 CFR 303.8) has been submitted to OMB and has been assigned a control number of 3084–0101.

List of Subjects in 16 CFR Part 303

Labeling, Textile, Trade practices.

Authority: Sec. 7(c) of the Textile Fiber Products Identification Act (15 U.S.C. 70e(c)).

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 96–17468 Filed 7–8–96; 8:45 am]

BILLING CODE 6750–01–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 51 and 93

[FRL–5527–9]

RIN 2060–AG16

Transportation Conformity Rule Amendment and Solicitation for Participation in the Transportation Conformity Pilot Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to amend the transportation conformity rule to allow EPA to create and implement a conformity pilot program. The conformity rule requires that transportation activities conform to state air quality implementation plans and establishes the criteria and procedures for determining whether or not they do. Conformity to an air quality plan means that transportation activities will not produce new air quality violations, worsen existing violations, or delay timely attainment of national ambient air quality standards.

The pilot program would exempt up to six areas from some of the existing rule's requirements. After EPA approval, the areas will experiment with alternative conformity procedures for the three-year duration of the program. Today's notice invites applications for participation in the pilot program and presents the application and selection process, which will be finalized in the final rule.

Along with recent amendments to the conformity rule, the pilot program is part of an EPA strategy to provide states and localities greater flexibility in meeting federal transportation conformity requirements while reinforcing Clean Air Act commitments.

This strategy results from experience gained in implementing the conformity rule.

The conformity pilot program would allow state and local transportation and air quality agencies the additional flexibility to seek out and test the conformity procedures that work best in their area. Participating areas' experiences will be evaluated and it is possible that successful pilot programs may ultimately lead to further changes in the conformity rule.

DATES: Comments on this action must be received by August 8, 1996. Applications may be submitted beginning July 9, 1996. EPA requests expressions of interest by August 23, 1996.

ADDRESSES: Interested parties may submit written comments (in duplicate, if possible) to: Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, Attention: Docket No. A–95–55, 401 M. Street, S.W., Washington, DC 20460.

Materials relevant to this proposal have been placed in Public Docket A–95–55 by EPA. The docket is located at the above address in room M–1500 Waterside Mall (ground floor) and may be inspected from 8 a.m. to 4 p.m., Monday through Friday, including all non-governmental holidays.

For informational purposes, areas which submit expressions of interest and applications will be listed on the EPA's Technology Transfer Network (TTN) bulletin board, on the Office of Mobile Sources (OMS) bulletin board under the Rulemaking: Transportation: Conformity file area. TTN files can be accessed on the first call to (919) 541–5742 or through the internet at TELNET ttnbbs.rtpnc.epa.gov. TTN is off-line every Monday from 8:00 a.m.–12 Noon, and the TTN voice help line is (919) 541–5384.

FOR FURTHER INFORMATION CONTACT: Elizabeth Cummings, Transportation and Market Incentives Group, Regional and State Programs Division, U.S. Environmental Protection Agency, 2565 Plymouth Road, Ann Arbor, MI 48105, (313) 741–7857 or Lucy Garliauskas, Environmental Analysis Division, Office of Environment and Planning, Federal Highway Administration, 400 Seventh Street S.W., Washington, DC 20590, (202) 366–2068.

SUPPLEMENTARY INFORMATION:

Regulated Entities

Entities potentially regulated by the conformity rule are those which adopt, approve, or fund transportation plans, programs, or projects under the Intermodal Surface Transportation Efficiency Act or Federal Transit Laws. Regulated categories and entities include:

Category	Examples of regulated entities
Local government	Local transportation and air quality agencies.
State government	State transportation and air quality agencies.
Federal government	EPA and Department of Transportation (Federal Highway Administration and Federal Transit Administration).

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by the conformity rule. Other types of entities not listed in the table could also be affected. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

The contents of today's preamble are listed in the following outline:

I. Background of Transportation Conformity

The transportation conformity rule, ''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 November 24, 1993 (58 FR 62188) and amended 40 CFR Parts 51 and 93. It was subsequently amended on August 7, 1995 (60 FR 40098) and November 14, 1995 (60 FR 57179). In addition, EPA is proposing a third set of conformity amendments to further streamline and simplify the conformity rule.

Required under section 176(c) of the Clean Air Act, as amended in 1990, the transportation conformity rule established the criteria and procedures by which the Federal Highway Administration (FHWA), the Federal Transit Administration (FTA), and metropolitan planning organizations (MPOs) determine the conformity of federally funded or approved highway and transit plans, programs, and projects to state implementation plans (SIPs). The Clean Air Act requires that federally supported activities conform to the implementation plan's purpose of expeditiously attaining and of maintaining the national ambient air quality standards.

Since publication of the transportation conformity rule in November 1993, EPA, the Department of Transportation (DOT), and state and local air and transportation officials have had considerable experience implementing the criteria and procedures in the rule. It is that mutual experience which has lead EPA and DOT to undertake a number of initiatives to streamline the transportation conformity rule. In addition to significant revisions of the conformity rule through three sets of amendments, today's proposal would provide further flexibility through the creation and implementation of a transportation conformity pilot program.

II. Conformity Pilot Program

The purpose of this notice is to propose an amendment to 40 CFR Parts 51 and 93 to create a transportation conformity pilot program. This amendment would allow EPA and DOT to select up to six areas to participate in the program and would allow EPA to exempt the selected areas from certain provisions of the transportation conformity regulation for a period of three years. This notice also describes the pilot program's objectives, application and selection process, and participation requirements, and solicits applications for the program.

A. Conformity Pilot Program Objective

The overall objective of the conformity pilot program would be to seek out and test innovative methods of streamlining regulatory requirements while ensuring that Clean Air Act objectives and requirements are met. EPA and DOT are committed to continuing to encourage procedures which improve the conformity process. Under the pilot program, state and local air and transportation agencies could identify the conformity processes and procedures that work best for their area, and EPA and DOT would select the applications expected to lead to a more effective conformity process. It is

possible that successful pilot projects may ultimately lead to further changes in the federal transportation conformity regulation.

The pilot program would enable as many as six areas to exercise flexibility in meeting certain requirements of the conformity regulation in three areas: modeling, consultation, and coordination of the Intermodal Surface Transportation Efficiency Act (ISTEA) schedules and procedures with conformity deadlines and schedules. EPA would also consider proposals from applicants to extend this flexibility to other aspects of the conformity requirements.

During the third year of the pilot program, EPA and DOT would conduct a national evaluation to see if transportation policy, project selection and investment choices changed as a result of a more flexible approach to meeting the Clean Air Act conformity requirements; if interagency consultation and public participation improved as a result of new procedures; and if Clean Air Act compliance costs were reduced and efficiencies implemented while still ensuring that Clean Air Act goals and requirements were met. Pilot program areas would also propose methods for self-evaluation of their conformity pilot program and cooperate with the national evaluation.

B. Exemption From Certain Conformity Requirements

This proposal would allow EPA and DOT to exempt no more than six areas for no more than three years from certain requirements of 40 CFR Parts 51 and 93, if these areas are selected to participate in this conformity pilot program. EPA and DOT approval of the alternative requirements developed by the applicant areas would be required for selection to participate in the pilot program. In order to obtain EPA and DOT approval, each area would be required to provide an opportunity for public comment on its proposed alternative conformity requirements. The alternative conformity requirements would be proposed to achieve results equivalent to or better than the requirements of 176(c) of the Clean Air Act. Areas selected to participate in the pilot program must comply with their final project agreements. After the three-year duration of the pilot program has expired, the selected areas would again be subject to all of the requirements of 40 CFR Parts 51 and 93. However, EPA may revise 40 CFR Parts 51 and 93 to incorporate elements of effective pilot programs based on results from evaluating the first two years of program implementation.

C. Eligibility

Up to six areas currently subject to the requirements of the transportation conformity regulation would be selected by EPA and DOT to participate in the pilot program. Applications may be submitted by either an MPO, a local air quality agency, a state air quality agency, or a state department of transportation acting as a lead contact for purposes of the pilot program. When submitting its application, the lead agency must demonstrate that its proposal is endorsed by all state and local air and transportation agencies that participate in the area's interagency consultation process. In certain cases, for example, an MPO that covers more than one nonattainment area or a nonattainment area that covers more than one state, EPA and DOT may subsequently request further endorsement from additional agencies affected by the proposal.

D. Submission of Applications

Applications may be submitted to Elizabeth Cummings, Transportation and Market Incentives Group, Regional and State Programs Division, U.S. Environmental Protection Agency, 2565 Plymouth Road, Ann Arbor, MI 48105. Applications will be accepted beginning July 9, 1996. EPA will begin accepting applications prior to final action on this rule amendment. If the final rule is different than this proposal, due to public comment received, areas that have already submitted applications may be asked to supplement their application materials.

EPA requests that areas considering applying to the pilot program submit a non-binding ''expression of interest'' before August 23, 1996. The ''expression of interest'' letter could be submitted by the lead agency and would not need to include any preliminary description or endorsement of the application. This would provide EPA and DOT with an approximate number of applications to expect. EPA would list the areas that have submitted expressions of interest and applications on EPA's Technology Transfer Network (TTN) bulletin board. EPA would also place copies of the submitted applications in the public docket. (See **ADDRESSES** for information on the TTN bulletin board and the public docket.)

Once EPA has taken final action on this proposal, EPA and DOT would be able to jointly select up to six pilot program participants on a rolling basis until six participants are selected, unless the agencies decide to select fewer than six participants. If fewer than six participants are selected in the first iteration of the selection process, EPA and DOT would continue to process applications on a rolling basis.

The following information will enable EPA and DOT to consider an application: (1) A particular proposal for flexibility in applying elements of the conformity regulation; (2) the rationale for change, including: (i) The particular problems in the existing requirements that the proposal intends to address, and (ii) the benefits that the alternative proposal would create (e.g., air quality benefits, resource savings); (3) a description of the alternative methods and/or procedures to be used in meeting conformity requirements; (4) the proposed schedule for making conformity determinations during the pilot program (for a period of up to three years); (5) evidence that sufficient resources to conduct the pilot program will be available (e.g., some of the pilot program activities may be eligible for title 23 State Planning and Research Funds (SPR) or Planning (PL) funds); (6) discussion of any potential implementation issues that must be overcome for the pilot program to be successful; (7) suggestions for self-evaluation of the pilot program; (8) evidence that the proposal is endorsed by all the state and local air and transportation agencies; and (9) evidence that key stakeholders have been or will be consulted and that appropriate public participation procedures will be undertaken, which may be incorporated into the area's normal interagency consultation process.

Applications should be in narrative form and should be concise while still containing sufficient information to fully describe the proposal. It is EPA and DOT's intent to use the application to conduct preliminary reviews. Further details of the proposal would be incorporated during the consultation stage of the selection process and would be subject to the project agreement, as described below. The extent to which the application addresses the information requested and the application length will depend upon the proposal's complexity.

E. Selection Criteria

Applications would be assessed according to the following criteria: (1) Whether the proposed flexibilities fulfill all the statutory requirements for transportation conformity; (2) the degree to which the application fulfills the pilot program's goals of testing innovative methods and streamlining the regulatory process, including, but not limited to, the specified areas of modeling, interagency/public

consultation, and coordination of ISTEA and Clean Air Act requirements; (3) the degree of key stakeholder and public support in the geographic area covered by the proposal; (4) whether the applicant has the resources necessary to effectively implement and evaluate the proposed conformity pilot program; (5) whether the area has adequately demonstrated its intent to comply with Clean Air Act objectives; and (6) the degree to which data and analysis will be provided to help assess air quality, resource savings, public participation, and other program benefits.

In order to assure that the pilot program provides an opportunity to test innovative approaches to conformity in a broad range of circumstances, EPA and DOT would attempt to select a group of participants that is diverse in terms of geographic distribution, nonattainment pollutants, nonattainment classifications, and rural and urban development.

F. Selection Process

The selection process would have three stages: application review, applicant consultation, and project agreement finalization. First, EPA and DOT will review submitted applications. Applications not selected by the agencies during the initial application review will be notified; all other applications will proceed to the consultation stage.

In the consultation stage, EPA and DOT will schedule a conference call with each applicant to clarify any questions about the applicant's proposal, permit the federal agencies to clarify their understanding of what the proposed conformity pilot program would entail, and to evaluate further the suitability of the proposal for inclusion in the pilot program. Then EPA and DOT will arrange for a subset of these applicants to present their proposals in a review session with federal agency staff. Representatives of the lead agency submitting the pilot program application and other public agencies involved in the applicant's geographic area would participate in the presentation. Based upon the information presented in the application and consultation stages, EPA and DOT could select up to six applicants to participate in the pilot program.

In the final stage, and following finalization of this rule amendment, EPA, DOT and the applicant agencies would negotiate the final project agreement, which would formalize each area's selection as a pilot program participant. Before EPA and DOT approve the final project agreement, the lead agency would be required to demonstrate that it has provided a public comment period of not less than 30 days on its proposed alternative conformity requirements. The lead agency would also be required to demonstrate how it solicited and took into account any public comments during the public comment period. Upon finalization, the project agreement would be fully enforceable under the Clean Air Act.

III. Conformity SIPs

Although this proposal would exempt pilot program participants from certain conformity rule requirements, it could not exempt a pilot program participant from requirements in its approved conformity SIP. Once EPA has approved the conformity SIP, the federal conformity rule no longer applies to those subjects covered by the conformity SIP, and the requirements in the conformity SIP have the force of federal and state law. Therefore, if an area's submitted conformity SIP has already been approved by EPA, a new SIP would need to be submitted and approved in order for an area to participate in the pilot program and be relieved of certain of its conformity SIP requirements. The area's final project agreement under the pilot program could be submitted as its new conformity SIP.

If a pilot program participant has already submitted a conformity SIP which EPA has not yet approved, then the conformity SIP (or certain portions of the conformity SIP applicable to the particular area) would need to be withdrawn for the duration of the pilot program in order to ensure that the area could be governed by the final project agreement.

Areas that are selected to participate in the pilot program and have not yet submitted a conformity SIP would be exempted from the requirements of § 51.396 (''Implementation plan revision'') so that they would not be required to submit a conformity SIP for the area for the duration of participation in the pilot program. In addition, areas that are selected to participate in the pilot program would be exempted for the duration of the pilot program from the requirement to submit a SIP revision in response to conformity rule amendments.

IV. Administrative Requirements

A. Executive Order 12866

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 otherwise 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 or entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof;

(4) Raise novel or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this rule is not a ''significant regulatory action'' under the terms of Executive Order 12866. EPA has submitted this action to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

B. Reporting and Recordkeeping Requirements

This rule does not contain any information collection requirements from EPA which require approval by OMB under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*

C. Regulatory Flexibility Act

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 today's regulations will not have a significant impact on a substantial number of small entities. This regulation affects federal agencies and metropolitan planning organizations, which by definition are designated only for metropolitan areas with a population of at least 50,000. These organizations do not constitute small entities.

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.

D. Unfunded Mandates

Under Sections 202, 203, and 205 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must undertake various actions in association with proposed or final rules that include a federal mandate that may result in estimated costs of $100 million or more to the private sector, or to State, local, or tribal governments in the aggregate.

EPA has determined that to the extent this rule imposes any mandate within the meaning of the Unfunded Mandates Act, this final action does not include a mandate that may result in estimated costs of $100 million or more to State, local, or tribal governments in the aggregate or to the private sector. Therefore, EPA has not prepared a statement with respect to budgetary impacts.

List of Subjects

40 CFR Part 51

Environmental protection, Administrative practice and procedure, Carbon monoxide, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

40 CFR Part 93

Administrative practice and procedure, Air pollution control, Carbon monoxide, Intergovernmental relations, Ozone.

Dated: June 21, 1996.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble, title 40, chapter I, Parts 51 and 93 of the Code of Federal Regulations are proposed to be amended as follows.

PARTS 51 AND 93—[AMENDED]

1. The authority citation for parts 51 and 93 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

2. Parts 51 and 93 are proposed to be amended by adding identical §§ 51.446 and 93.137 to read as follows:

§ . Special exemptions from conformity requirements for pilot program areas.

EPA and DOT may exempt no more than six areas for no more than three years from certain requirements of this subpart if these areas are selected to participate in a conformity pilot program and have developed alternative requirements that have been approved by EPA and DOT. In order to obtain EPA and DOT approval on its final project agreement, each area must provide a 30-day public comment period and address comments received on its proposed alternative conformity requirements. The alternative conformity requirements must be proposed to fulfill all of the requirements of and achieve results equivalent to or better than section 176(c) of the Clean Air Act. Areas selected to participate in the pilot program must comply with their final project agreements. After the three-year duration of the pilot program has expired, areas will be subject to the requirements of this subpart.

[FR Doc. 96–16591 Filed 7–8–96; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 52

[WA3–1–5479; FRL–5534–9]

Approval and Promulgation of State Implementation Plans: Washington

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed rulemaking.

SUMMARY: In this action, Environmental Protection Agency (EPA) invites public comment on its proposed approval of certain elements of the Spokane PM–10 attainment plan, including control measures, and the granting of a temporary waiver of the attainment date for the Spokane, Washington particulate nonattainment area. This is based on EPA's review of the State implementation plan (SIP) revision submitted by the State of Washington for the purpose of attaining the national ambient air quality standards (NAAQS) for particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers (PM–10). The implementation plan was submitted by the State to satisfy certain federal Clean Air Act requirements for an approvable moderate nonattainment area PM–10 SIP for Spokane, Washington due on November 15, 1991.

DATES: Comments on this proposed action must be postmarked by August 8, 1996.

ADDRESSES: Written comments should be addressed to: Montel Livingston, SIP Manager, United States Environmental Protection Agency, Office of Air Quality (OAQ 107), 1200 Sixth Avenue, Seattle, Washington 98101.

Copies of the State's submittals and other information supporting this proposed action are available for inspection during normal business hours at the following locations: United States Environmental Protection Agency, Office of Air Quality, 1200 Sixth Avenue (AT–082), Seattle, Washington 98101, and the State of Washington Department of Ecology, 300 Desmond Drive, Lacey, Washington 98503.

FOR FURTHER INFORMATION CONTACT: George Lauderdale, Office of Air Quality (OAQ 107), US Environmental Protection Agency, 1200 Sixth Avenue, Seattle, Washington 98101, (206) 553–6511.

SUPPLEMENTARY INFORMATION:

I. Background

The Spokane, Washington, area was designated nonattainment for PM–10 and classified as moderate under sections 107(d)(4)(B) and 188(a) of the Clean Air Act, by operation of law upon enactment of the Clean Air Act Amendments of 1990.[1] See 56 FR 56694 (Nov. 6, 1991)(official designation codified at 40 CFR 81.348). The air quality planning requirements for moderate PM–10 nonattainment areas are set out in subparts 1 and 4 of Part D, Title I of the Act.[2] The EPA has issued a ''General Preamble'' describing EPA's preliminary views on how EPA intends to review SIP's and SIP revisions submitted under Title I of the Act, including those State submittals containing provisions to implement the moderate PM–10 nonattainment area SIP requirements [see generally 57 FR 13498 (April 16, 1992) and 57 FR 18070 (April 28, 1992)]. Because EPA is describing its interpretations here only in broad terms, the reader should refer to the General Preamble for a more detailed discussion of the interpretations of Title I advanced in this proposal and the supporting rationale. In this rulemaking action on the Washington moderate area PM–10 SIP revision for the Spokane nonattainment area, EPA is proposing to apply its interpretations, taking into consideration the specific factual issues presented. Additional information supporting EPA's action on this particular area is available for inspection at the address indicated above. EPA will consider any timely

[1] The 1990 Amendments to the Clean Air Act made significant changes to the Act. See Pub. L. No. 101–549, 104 Stat. 2399. References herein are to the Clean Air Act, as amended (''the Act''). The Clean Air Act is codified, as amended, in the U.S. Code at 42 U.S.C. sections 7401, *et seq.*

[2] Subpart 1 contains provisions applicable to nonattainment areas generally and subpart 4 contains provisions specifically applicable to PM–10 nonattainment areas. At times, subpart 1 and subpart 4 overlap or conflict. EPA has attempted to clarify the relationship among these provisions in the ''General Preamble'' and, as appropriate, in today's notice and supporting information.

submitted comments before taking final action on today's proposal.

Those States containing initial moderate PM–10 nonattainment areas (those areas designated nonattainment under section 107(d)(4)(B)) were required to submit an implementation plan that includes, among other things, the following by November 15, 1991:

1. Provisions to assure that reasonably available control measures (RACM) (including such reductions in emissions from existing sources in the area as may be obtained through the adoption, at a minimum, of reasonably available control technology—RACT) shall be implemented no later than December 10, 1993;

2. Either a demonstration (including air quality modeling) that the plan will provide for attainment as expeditiously as practicable but no later than December 31, 1994, or a demonstration that attainment by that date is impracticable;

3. Quantitative milestones which are to be achieved every 3 years and which demonstrate reasonable further progress (RFP) toward attainment by December 31, 1994; and

4. Provisions to assure that the control requirements applicable to major stationary sources of PM–10 also apply to major stationary sources of PM–10 precursors except where the Administrator determines that such sources do not contribute significantly to PM–10 levels which exceed the NAAQS in the area. See sections 172(c), 188, and 189 of the Act.

Some provisions were due at a date later than November 15, 1991. States with initial moderate PM–10 nonattainment areas were required to submit a permit program for the construction and operation of new and modified major stationary sources of PM–10 by June 30, 1992 (see section 189(a)). Such States also were to submit contingency measures by November 15, 1993, which become effective without further action by the State or EPA upon a determination by EPA that the area has failed to achieve RFP or to attain the PM–10 NAAQS by the applicable statutory deadline (see section 172(c)(9) and 57 FR 13543–44).

II. Today's Action

Section 110(k) of the Act sets out provisions governing EPA's review of SIP submittals (see 57 FR 13565–66). For PM–10 nonattainment areas, Section 188(f), Waivers for Certain Areas, can apply as well.

In this action, EPA is proposing to approve portions of the PM–10 nonattainment area plan for Spokane, Washington that apply to sources of PM–10 other than windblown dust. For PM–10 24-hour exceedences caused primarily by windblown dust sources EPA is proposing to grant a temporary waiver of the attainment date for the Spokane area. Discussion of EPA's requirements for a temporary waiver are detailed in 59 FR 41998–42017 (August 16, 1994). In this guidance EPA provides certain flexibility for areas where the relative significance of anthropogenic and nonanthropogenic sources is unknown. The Washington Department of Ecology (Ecology) has presented preliminary data, based on an analysis of the relative contributions of anthropogenic and nonanthropogenic sources of PM–10 contributing to eastern Washington exceedences, indicating that nonanthropogenic sources may be significant in the Spokane nonattainment area during windblown dust events. EPA proposes to accept this preliminary information and grant a temporary waiver of the moderate area attainment date to December 31, 1997. This temporary waiver allows Ecology and EPA to evaluate further the windblown dust PM–10 problems in the Spokane PM–10 nonattainment area. Once the evaluation is completed and reviewed, and/or the temporary waiver expires, EPA will make a final determination on the designation and classification for the Spokane nonattainment area.

In order to move forward with consideration of the temporary waiver, a Memorandum of Agreement was signed in August 1995, by Chuck Clarke, Regional Administrator EPA, Region 10, and Mary Riveland, Director, Washington State Department of Ecology. This agreement outlines the approach each agency will take in completing work on the PM–10 problems in both the Spokane and Wallula nonattainment areas. The agreement contains commitments and conclusions including:

> EPA will propose and, subject to public comment, grant a conditional, temporary, waiver of the attainment date for 24-hour PM–10 exceedances during windblown dust events for Spokane and Wallula until the end of 1997 (12/31/97). The waiver would expire on 12/31/97, and throughout its effective period, will apply only where windblown dust (both anthropogenic and nonanthropogenic) is an important contributor to the exceedances.
>
> The Spokane and Wallula nonattainment areas will retain the classification of a moderate PM–10 nonattainment area, until 12/31/97 unless PM–10 air quality data indicates that the area has failed to attain the 24-hour health standard because of exceedances that cannot be primarily attributed to windblown dust.

As required in the EPA guidance, Ecology and EPA are proceeding under written agreements which include a protocol for both technical analysis (emission inventory, emission factor development, dispersion modeling, receptor modeling, etc.) and evaluation of alternative control measures, including Best Available Control Measures. The activities required under the protocol are generally referred to as the Columbia Plateau PM–10 Project funded by EPA, Ecology, and the U.S. Department of Agriculture (USDA). Cooperating agencies include USDA's Agricultural Research Service and Natural Resources Conservation Service, as well as several local conservation districts, Washington State University, the University of Idaho, and others.

The temporary waiver of the attainment date, if finalized by EPA, will defer approval/disapproval actions on several otherwise required elements of the moderate area plan for Spokane. Since the purpose of the above described MOA is to have control measures in place that assure that the PM–10 NAAQS will not be violated from sources that are primarily urban in nature, the submission of an attainment demonstration, emission inventory, and contingency measures for such urban sources are necessary and required. However, if the temporary waiver is finalized, the attainment demonstration, emission inventory, control measures and contingency measures for windblown dust sources (e.g. agriculture and natural sources) will be deferred. EPA will take final action on the windblown dust elements after the Columbia Plateau analysis is completed and/or the expiration of the temporary waiver. EPA's reasoning for this approach is described in more detail under the various SIP element headings of this notice.

In this action EPA is also proposing to approve regulatory orders for the Kaiser, Trentwood facility that will allow use of alternative opacity standards under certain very specific conditions. These orders will lower the allowable emissions from the facility and thus would not have an adverse impact on the attainment demonstration for other than windblown dust sources in the Spokane area.

EPA is also proposing to approve the exclusion from precursor controls as described in part II. 5 below. EPA invites public comment on the proposed action described in this section.

This action is EPA's response to Washington State Implementation Plan revision submitted for the Spokane PM–10 nonattainment area on November 15, 1991, January 31, 1992, and December 9,

1994. In addition, supplemental information was submitted by Ecology on May 18, 1995.

A. Analysis of State Submission

1. Procedural Background

The Act requires States to observe certain procedural requirements in developing implementation plans and plan revisions for submission to EPA. Section 110(a)(2) of the Act provides that each implementation plan submitted by a State must be adopted after reasonable notice and public hearing.[3] Section 110(l) of the Act similarly provides that each revision to an implementation plan submitted by a State under the Act must be adopted by such State after reasonable notice and public hearing. The EPA also must determine whether a submittal is complete and therefore warrants further EPA review and action (see section 110(k)(1) and 57 FR 13565). The EPA's completeness criteria for SIP submittals are set out at 40 CFR Part 51, Appendix V (1992). The EPA attempts to make completeness determinations within 60 days of receiving a submission. However, a submittal is deemed complete by operation of law if a completeness determination is not made by EPA six months after receipt of the submission.

Ecology held a public hearing to receive public comment on the November 15, 1991, Spokane PM–10 SIP revision on October 23, 1991. WDOE adopted the SIP revision for the area on November 14, 1991, and the plan was submitted to EPA on November 15, 1991. Ecology submitted an addendum to the November SIP revision that contained a regulatory order on January 31, 1992. The SIP revision submittals were reviewed by EPA to determine completeness in accordance with the completeness criteria set out at 40 CFR Part 51, Appendix V. A letter dated May 5, 1992, was forwarded to the WDOE indicating the completeness of the submittals and the next steps to be taken in the review process. On December 9, 1994, Ecology submitted another SIP revision for the Spokane PM–10 nonattainment area. This 1994 revision contained additional control measures, a more detailed technical analysis of the problem, and other improvements to the November 15, 1991 submittal.

2. PM–10 Emissions Inventory

Section 172(c)(3) of the Act requires that nonattainment plan provisions include a comprehensive, accurate, current inventory of actual emissions from all sources of relevant pollutants for the base year in the nonattainment area. Because the submission of the emissions inventory is a necessary adjunct to an area's attainment demonstration (or demonstration that the area cannot practicably attain) the emissions inventory must be received with the demonstration (see 57 FR 13539).

In the December 9, 1994, Spokane plan Ecology submitted an emissions inventory of all PM–10 sources, except windblown dust, which estimated actual annual emissions for the base year of 1990, allowable emissions for the attainment year of 1994 and allowable emissions for the 3-year maintenance year of 1997. Ecology concluded that, after excluding windblown dust, Spokane has three very different emission scenarios that could cause PM–10 short-term, 24-hour standard violations. Each scenario occurs at a different time of the year, has different meteorological conditions, and each has one source that dominates the source mix. Ecology illustrated the three scenarios by presenting separate 24 hour emission inventories for the following worst case days: an October 21, 1987 inventory for conditions where unpaved roads were the major source, a March 12, 1993 inventory where paved roads were the dominant source, and a January 21, 1987 analysis for residential wood combustion exceedences.

For windblown dust, Ecology prepared and submitted as an appendix to the Spokane plan, a report titled ''An Analysis of the Impact of Biogenic PM–10 Sources on the Spokane PM–10 Nonattainment Area'', February 1992, which presented the most recent information on the emission sources in the Columbia Plateau region of eastern Washington. The report estimates gross annual emissions from anthropogenic and nonanthropogenic sources of PM–10 from a large area. Preliminary information is presented indicating that about 40% of the annual emissions in eastern Washington are from anthropogenic sources and 60% from nonanthropogenic sources. No attempt was made to estimate the highest 24-hour emissions which, depending on the location, is expected to vary greatly. This information suggests, but does not conclusively show, that nonanthropogenic sources contribute significantly to the Spokane nonattainment area.

In summary, the 1994 annual emission inventory, excluding windblown dust, indicated that the largest sources of PM–10 were: unpaved roads (43%), paved roads (20%), residential wood combustion (18%) and industrial (14%). The SIP revision also includes 24-hour emission inventories for each of the three scenarios mentioned above.

The emissions inventory estimating actual emissions for all significant sources except for windblown dust sources appears to be accurate and comprehensive consistent with the requirements of section 172(c)(3) of the Clean Air Act and national guidance.[4] Recent information from the Columbia Plateau study indicates that the emission factors used for the windblown dust report may be inappropriate. However, EPA thinks that the assumptions used were the best available at the time the Spokane plan was prepared. The Columbia Plateau PM–10 Project will include the development of emission factors specifically for eastern Washington and preparation of regional emission inventories that will be used to update the Spokane plan.

One final emission inventory issue relates to the use of actual emission estimates from two major stationary (stack) PM–10 sources. Ecology appropriately used allowable emissions for most of the stationary sources that had allowable emission limits. However, Ecology underestimated the allowable emissions for the two major stationary PM–10 sources, the Kaiser primary aluminum smelter at Mead, and the Kaiser aluminum rolling mill facility at Trentwood. Supplemental information submitted on May 18, 1995, concludes that the allowable emissions for those facilities are greater (by a factor of 2 for Kaiser-Trentwood) than the emissions used in the plan. The Spokane County Air Pollution Control Agency (SCAPCA) has corrected this problem for the Kaiser-Trentwood facility by issuing new regulatory orders which specifically limit the PM–10 emissions from the facility. The allowable emissions from the Kaiser-Mead facility are not significantly greater than the original allowable emission estimates used by Ecology and would not adversely impact the attainment demonstration for sources considered in the plan.

EPA proposes to approve the emission inventories, excluding windblown dust, at this time. The windblown dust inventory is being prepared as part of the Columbia Plateau project. When the project is completed the detailed

[3] Section 172(c)(7) of the Act requires that plan provisions for nonattainment areas meet the applicable provisions of section 110(a)(2).

[4] The EPA issued guidance on PM–10 emissions inventories prior to the enactment of the Clean Air Act Amendments in the form of the 1987 *PM–10 SIP Development Guideline.* The guidance provided in this document is consistent with the Act.

emission inventory will be used for analysis of windblown dust. Therefore EPA proposes to defer action on the windblown dust emission inventory until after the temporary waiver expires.

3. RACM (Including RACT)

As noted above, the initial moderate PM–10 nonattainment areas must submit provisions to assure that RACM (including RACT) are implemented no later than December 10, 1993 (see sections 172(c)(1) and 189(a)(1)(C)). The General Preamble contains a detailed discussion of EPA's interpretation of the RACM (including RACT) requirement (see 57 FR 13539–45 and 13560–61).

The Spokane annual emission inventory identified four urban (non windblown dust) sources as major contributors of PM–10 emissions; paved roads, unpaved roads, residential wood combustion and industrial sources. However, analysis of the 24-hour PM–10 problems conclude that industrial sources are not a major contributor. Ecology prepared RACM evaluations for paved and unpaved roads and residential wood combustion sources. Ecology did not present an evaluation of the controls that are currently being applied to agricultural sources likely impacting the Spokane PM–10 problem. For unpaved roads, the City of Spokane has spent more than six million dollars to pave over 16 miles of roads. Road paving is estimated to result in a PM–10 reduction of at least 90% from an unpaved road surface.

SCAPCA also adopted an unpaved road control regulation which requires that the City of Spokane, Spokane County, and the Town of Millwood submit emission reduction and control plans for unpaved surfaces in their respective jurisdiction. SCAPCA approves the plans and the respective jurisdictions are required to implement the plans. In addition, to address the paved road emissions the City of Spokane adopted resolutions committing to conduct additional (more frequent and earlier) street sweeping to better control PM–10. The City also committed to reduce the use of sand for traction material by 50%, increase the use of liquid deicers, plow major arterials more frequently, and sweep the arterial as soon as practical after sanding.

EPA proposes to accept Ecology's RACM analysis for paved and unpaved roads and concludes that reasonable measures are being implemented.

Residential wood combustion is regulated by SCAPCA through a comprehensive regulation that is based on state statute. The program contains limitations on opacity, curtails wood burning on days of poor air quality, prohibits the burning of inappropriate fuels, and other emission reducing measures. Curtailment of uncertified woodstoves and fireplaces is initiated when PM–10 levels are estimated to be 75 ug/m3. Ecology estimates an 80% reduction in emissions for the program. EPA proposes to determine that Spokane is implementing RACM for residential wood combustion sources.

The only two major (greater than 100 tons per year) stationary source facilities within the nonattainment area, the Kaiser aluminum facilities at Trentwood and Mead, were not evaluated specifically for RACT by either Ecology or SCAPCA. However, attainment is demonstrated for the PM–10 sources other than windblown dust, using allowable emissions from the facilities. Therefore a RACT determination is not necessary and the SIP revision does not include any additional emission reductions from any stationary sources. It is important to note that the Kaiser Trentwood facility is under a federal consent decree and final judgement which will reduce PM–10 emissions from the facility in the future.

The final source of PM–10 impacting the Spokane nonattainment area is windblown dust. There are two principal sources of windblown dust: undisturbed land and agricultural fields. Ecology did not perform a RACM analysis for agricultural sources in the Spokane nonattainment plan. However, Ecology had previously submitted an analysis of RACM for agricultural sources for the Wallula, Washington, PM–10 nonattainment area which has similar windblown dust issues. In that SIP revision Ecology concluded that RACM is being applied for agriculture sources of PM–10 based on soil conservation measures required by the federal government's implementation of the United States Department of Agriculture's (USDA) Food Security Act (FSA) of 1985. EPA Title I preamble guidance suggests states ''rely upon the soil conservation requirements (e.g. conservation plans, conservation reserve) of the Food Security Act to reduce emissions from agricultural operations'' (see 57 FR 18072).

EPA proposes to determine that RACM is being applied to agricultural sources not only in the Spokane nonattainment area but throughout the region surrounding Spokane. Ecology did not evaluate the application of reasonable controls on undisturbed lands. This analysis will be accomplished after completion of the Columbia Plateau PM–10 Project.

Where sources of PM–10 contribute insignificantly to the PM–10 problem in the area, EPA's policy is that it would be unreasonable (and would not constitute RACM) to require the implementation of potentially available control measures. 57 FR 13540. Further, EPA has indicated that for some sources in areas which demonstrate attainment, RACM does not require the implementation of otherwise available control measures that are not ''reasonably'' available because their implementation would not expedite attainment (See 57 FR 13543).

EPA is proposing to grant a temporary waiver of the attainment date to December 31, 1997, which will allow Ecology and EPA to determine conclusively the significance of anthropogenic and nonanthropogenic sources impacting Spokane. This action does not relieve the area from the requirement to implement RACM. In the Spokane situation EPA is proposing to determine that the major sources of PM–10 have been reasonably controlled. Thus, EPA thinks it would not be reasonable to require other smaller sources of PM–10 in the area to implement reasonably available control measures or technology. Further, EPA believes implementation of such additional controls in this area would not expedite attainment.

A more detailed discussion of the individual source contributions, their associated control measures and an explanation as to why certain available control measures were not implemented, can be found in the Spokane SIP revision. EPA has reviewed the State's explanation and associated documentation and is proposing to conclude that it adequately justifies the control measures being implemented.

4. Demonstration

As noted, the initial moderate PM–10 nonattainment areas must submit a demonstration (including air quality modeling) showing that the plan will provide for attainment as expeditiously as practicable but no later than December 31, 1994 (see section 189(a)(1)(B) of the Act). The General Preamble sets out EPA's guidance on the use of modeling for moderate area attainment demonstrations (57 FR 13539). Alternatively, if the State does not submit a demonstration of attainment, the State must show that attainment by December 31, 1994 is impracticable (section 189(a)(1)(B)(ii).

The SIP utilized dispersion modeling for demonstrating attainment for all major sources of PM–10 except windblown dust. As mentioned in the emission inventory discussion above, Spokane has different sources that are major contributors at different times of

the year. Ecology provided an attainment demonstration which included each of the three source scenarios. The attainment demonstration included days when residential wood combustion emissions dominated the area, also days when unpaved roads were the major source, and days dominated by paved road emissions. The dispersion modeling analysis demonstrated attainment of the 24-hour standard. EPA proposes to find the attainment demonstration for the major PM–10 sources, except for windblown dust, is adequate.

The attainment evaluation does not address the windblown dust issue including the anthropogenic and nonanthropogenic mix. In the 1994, Spokane SIP submittal, Ecology demonstrated attainment of the annual and 24-hour PM–10 standards for all sources of PM–10 except windblown dust by December 31, 1994. Ecology did not address exceedences of the 24-hour standard that were primarily due to windblown dust. As mentioned previously, EPA is proposing to temporarily set aside certain SIP requirements for windblown dust sources, including the attainment demonstration.

Since EPA is proposing to grant a temporary, three year waiver of the attainment date, EPA is also proposing that the approval or disapproval of the attainment demonstration for windblown dust PM–10 exceedences, be deferred until after expira-tion of the temporary waiver. EPA proposes to make a final decision on the attainment status and classification of the area after the temporary waiver expires on December 31, 1997. The alternative decisions include, but are not limited to, reclassi-fying the area to a serious PM–10 nonattainment area; applying the May 30, 1996, Memorandum from Mary D. Nichols, Assistant Administrator for Air and Radiation, regarding ''Areas Affected by PM–10 Natural Events; or granting the area a permanent waiver. EPA invites comments on these possible approaches.

5. PM–10 Precursors

The control requirements which are applicable to major stationary sources of PM–10, also apply to major stationary sources of PM–10 precursors unless EPA determines such sources do not contribute significantly to PM–10 levels in excess of the NAAQS in that area (see section 189(e) of the Act). The General Preamble contains guidance addressing how EPA intends to implement section 189(e) (see 57 FR 13539–40 and 13541–42).

The relatively small contribution of stationary sources in the Spokane nonattainment area suggests that stationary sources of precursors provide an insignificant contribution to the Spokane ambient PM–10 concentration. This conclusion is also supported by limited receptor analysis conducted in 1993. Based on that information Ecology concluded that the only major stationary source of PM–10 precursors, Kaiser-Mead, does not contribute significantly to PM–10 levels.

EPA is proposing to grant the area an exclusion from PM–10 precursor control requirements authorized under section 189(e) of the act. Note that while EPA is proposing to make a general finding for this area, this proposed finding is based on the current character of the area including, for example, the existing mix of sources in the area. It is possible, therefore, that future growth could change the significance of precursors in the area. EPA intends to issue future guidance addressing such potential changes in the significance of precursor emissions in an area.

6. Quantitative Milestones and Reasonable Further Progress (RFP)

The PM–10 nonattainment area plan revisions demonstrating attainment must contain quantitative milestones which are to be achieved every three (3) years until the area is redesignated attainment and which demonstrate RFP, as defined in section 171(1), toward attainment by December 31, 1994 (see section 189(c) of the Act). Reasonable further progress is defined in section 171(1) as such annual incremental reductions in emissions of the relevant air pollutant as are required by Part D or may reasonably be required by the Administrator for the purpose of ensuring attainment of the applicable NAAQS by the applicable date.

In the Spokane situation, EPA is proposing to approve the reasonable further progress requirement for all significant sources of PM–10 except windblown dust. The dispersion modeling conducted by Ecology indicates that the 24-hour standard was attained in 1994 and air quality will be maintained below the standard until at least 1997 (except for windblown dust). As stated previously, EPA is proposing to grant a temporary waiver of the attainment date for the Spokane area for windblown dust sources. If granted, the area would not be required to meet RFP for windblown dust sources. In 1998 EPA will determine the designation and classification of the Spokane area.

7. Enforceability Issues

All measures and other elements in the SIP must be enforceable by Ecology and EPA (see sections 172(c)(6), 110(a)(2)(A) and 57 FR 13556). EPA criteria addressing the enforceability of SIP's and SIP revisions were stated in a September 23, 1987 memorandum (with attachments) from J. Craig Potter, Assistant Administrator for Air and Radiation, et al. (see 57 FR 13541). Nonattainment area plan provisions must also contain a program that provides for enforcement of the control measures and other elements in the SIP (see section 110(a)(2)(C)).

Ecology's and SCAPCA's control measures and regulations for control of particulate matter, which are contained in the SIP, are addressed above under the section headed ''RACM (including RACT).'' These control measures apply to the types of activities identified in that discussion including, for example, fugitive emissions from unpaved roads. The SIP provides that the affected activities will be controlled throughout the entire nonattainment area.

The Clean Air Act requires that all the applicable RACM provisions be implemented by December 10, 1993 (section 189(a)(1)(C). In addition to the applicable control measures, this includes the applicable record-keeping requirements which are addressed in the supporting technical information document (TSD).

EPA is proposing to approve a December 12, 1991, SCAPCA Order No. 91–01. This order provides for the use of an alternate opacity limit for the Kaiser-Trentwood aluminum facility. EPA has evaluated information presented in the 1994 SIP revision for Spokane and other information and has concluded that the order will not have a significant impact on the ambient air quality in Spokane. EPA is further proposing to approve SCAPCA Order #96–03, Order #96–04, Order #96–05, and Order #96–06, for the Kaiser-Trentwood facility which will significantly lower the allowable emissions from the facility. The new allowable emission totals are the same as the amount used by Ecology in the attainment demonstration. Upon final approval by EPA as part of the SIP, the orders will be federally enforceable.

The TSD contains further information on enforceability requirements including enforceable emission limitations; a description of the rules contained in the SIP and the source types subject to them; test methods and compliance schedules; malfunction provisions; excess emission provisions; correctly cited references of

incorporated methods/rules; and reporting and recordkeeping requirements. Ecology and SCAPCA have the primary responsibility for implementing the measures in the plan. Ecology and SCAPCA have compliance inspectors and EPA considers the staffing level adequate to assure that the RACM provision in the Spokane attainment plan are fully implemented. As a necessary adjunct of its enforcement program, Ecology and SCAPCA also have broad powers to adopt rules and regulations, issue orders, require access to records and information, and receive and disburse funds.

8. Contingency Measures

As provided in section 172(c)(9) of the Act, all moderate nonattainment area SIP's that demonstrate attainment must include contingency measures (see generally 57 FR 13543–44). Contingency measures should consist of other available measures that are not part of the area's control strategy. These measures must take effect without further action by the State or EPA, upon a determination by EPA that the area has failed to make RFP or attain the PM–10 NAAQS by the applicable statutory deadline.

Ecology submitted several measures that were identified as contingency measures. As with their control measures necessary to demonstrate attainment, Ecology and SCAPCA, adopted contingency measures for each of the three significant sources of PM–10 other than windblown dust. The contingency measures include additional treatment of unpaved roads, early implementation of paved road controls (additional reductions from what is included in the attainment program) and banning the use of uncertified stoves if an exceedence is primarily due to residential wood combustion sources.

The plan does not contain a contingency measure for windblown dust. Since the action proposed in this Federal Register notice would allow for a temporary extension of the attainment date for windblown dust sources, EPA proposes to take no action on a contingency measure for windblown dust until after the temporary waiver has elapsed.

III. Implications of Today's Action

EPA is proposing to approve those portions of the 1994 PM–10 attainment plan for Spokane submitted by Ecology to control significant sources of PM–10 except for windblown dust, as meeting RACM and demonstrating attainment of the 24-hour standard by the statutory deadline of December 31, 1994. EPA is further proposing to grant a temporary waiver of the December 31, 1994, attainment date to December 31, 1997 for windblown dust-caused exceedences of the PM–10 24-hour standard. If this action is finalized, Ecology and SCAPCA will continue to implement the adopted control measures and Ecology will determine the significance of anthropogenic and nonanthropogenic windblown dust sources impacting the Spokane PM–10 nonattainment area. If any of the non-windblown dust sources cause any exceedences of the PM–10 24-hour standard the area could be reclassified to a serious PM–10 nonattainment area. When Ecology has completed its analysis on windblown dust, and/or the temporary waiver expires, EPA will make a final determination of the nonattainment status of the Spokane area. EPA is also proposing to approve several SCAPCA orders, including an alternate opacity order for the Kaiser-Trentwood facility in Spokane. Finally, EPA is proposing to grant an exclusion from precursor control requirements as described in part II. 5 of this notice.

IV. Request for Public Comments

EPA is requesting comments on all aspects of today's proposal. As indicated at the beginning of this notice, EPA will consider any comments postmarked by August 8, 1996.

V. Administrative Review

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.

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 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. section 7410(a)(2).

Under Section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the proposed action promulgated does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new Federal requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

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.

This action has been classified as a Table 3 action by the Regional Administrator under the procedures published in the Federal Register on January 19, 1989 (54 FR 2214–2224), as revised by a July 10, 1995 memorandum from Mary Nichols, Assistant Administrator for Air and Radiation. The Office of Management and Budget (OMB) has exempted this regulatory action from E.O. 12866 review.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Particulate matter.

Authority: 42 U.S.C. 7401–7671q.

Dated: June 27, 1996.
Jane S. Moore,
Acting Regional Administrator.
[FR Doc. 96–17459 Filed 7–8–96; 8:45 am]
BILLING CODE 6560–50–P

40 CFR Parts 52 and 81

[CO43–2–6865; CO43–1–6931; FRL–5532–07]

Clean Air Act Approval and Promulgation of State Implementation Plan for Colorado; Carbon Monoxide Attainment Demonstrations and Related SIP Elements for Denver and Longmont; Clean Air Act Reclassification

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Environmental Protection Agency today proposes approval of the State Implementation Plan (SIP) revisions submitted by the State of Colorado for the purpose of bringing about the attainment of the national ambient air quality standards (NAAQS) for carbon monoxide (CO). The implementation plan revisions were submitted by the State to satisfy certain Federal requirements for an approvable nonattainment area CO SIP for Denver and Longmont. This action includes proposed approval of revisions to Colorado Regulations 11 (vehicle inspection and maintenance) and 13 (oxygenated fuels) submitted to satisfy conditions in the SIP. It also includes proposed reclassification of the Denver CO nonattainment area from Moderate to Serious. The rationale for the approvals and reclassification are set forth in this document. Additional information is available at the address indicated below.

DATES: Comments on this proposed action must be received in writing by August 8, 1996.

ADDRESSES: Comments should be addressed to: Richard R. Long, Director of Air Programs (8P2–A), Environmental Protection Agency, Region VIII, 999 18th Street, Suite 500, Denver, Colorado 80202–2466.

Copies of the State's submittals and other information are available for inspection during normal business hours at the following locations: Environmental Protection Agency, Region VIII, Air Programs, 999 18th Street, 3rd Floor, South Terrace, Denver, Colorado 80202–2466; and Colorado Air Pollution Control Division, 4300 Cherry Creek Dr. South, Denver, Colorado 80222–1530.

FOR FURTHER INFORMATION CONTACT: Jeff Houk at (303) 312–6446.

SUPPLEMENTARY INFORMATION:

I. Background

The air quality planning requirements for moderate CO nonattainment areas are set out in sections 186–187 of the Clean Air Act (Act) Amendments of 1990 (CAAA) which pertain to the classification of CO nonattainment areas and to the submission requirements of the SIP's for these areas, respectively. The EPA has issued a ''General Preamble'' describing EPA's preliminary views on how EPA intends to review SIP's and SIP revisions submitted under Title I of the Act, [see generally 57 FR 13498 (April 16, 1992) and 57 FR 18070 (April 28, 1992)]. Because EPA is describing its interpretations here only in broad terms, the reader should refer to the General Preamble for a more detailed discussion of the interpretations of Title I advanced in today's proposal and the supporting rationale. In today's rulemaking action on the Denver and Longmont CO SIPs, EPA is proposing to apply its interpretations taking into consideration the specific factual issues presented. Thus, EPA will consider any timely submitted comments before taking final action on today's proposal.

This Federal Register document specifically addresses several requirements of the 1990 CAAA which were required to be submitted no later than November 15, 1992, and which the State did not submit by that date. These requirements include an attainment demonstration, contingency measures and, for Denver, a vehicle miles travelled forecasting and tracking program and transportation control measures. EPA made a formal finding that the State had failed to submit these SIP revisions in a letter to Governor Roy Romer dated January 15, 1993. This Federal Register document also addresses revisions to Regulations 11 and 13, submitted by the State of Colorado to implement portions of the control strategy relied upon by the attainment demonstration.

Section 187(a)(7) required those States containing CO nonattainment areas with design values greater than 12.7 parts per million (ppm) to submit, among other things, an attainment demonstration by November 15, 1992, demonstrating that the plan will provide for attainment by December 31, 1995 for moderate CO nonattainment areas and December 31, 2000 for serious CO nonattainment areas. The attainment demonstration must include a SIP control strategy, which is also due by November 15, 1992. The SIP control strategy for a given nonattainment area must be designed to ensure that the area meets the specific annual emissions reductions necessary for reaching attainment by the deadline. In addition, section 187(a)(3) requires these areas to implement contingency measures if any estimate of actual vehicle miles travelled (VMT) or any updated VMT forecast for the area contained in an annual report for any year prior to attainment exceeds the number predicted in the most recent VMT forecast. Contingency measures are also triggered by failure to attain the NAAQS for CO by the attainment deadline. Contingency measures must be submitted with the CO SIP by November 15, 1992. Finally, a vehicle miles travelled forecasting and tracking program is required by Section 187(a)(2)(A), and transportation control measures are required for Denver by Section 187(a)(2)(B). These requirements are discussed in more detail below and in the Technical Support Document for this proposed action.

Longmont had been designated as unclassifiable/attainment prior to passage of the 1990 CAAA. However, a special monitoring study in 1988–89 recorded an exceedance of the NAAQS in Longmont. As a result, EPA Region VIII recommended that the Governor designate this area nonattainment, and on March 15, 1991, the Governor submitted a nonattainment designation for this area that was later codified by EPA at 40 CFR Part 81. Since this area had never had a SIP, EPA interpreted Section 172 of the Act to require an attainment demonstration for Longmont. Contingency measures under Section 172(c)(9) were also required. On January 15, 1993, EPA made a formal finding that the State had failed to submit these SIP revisions for Longmont.

On July 11, 1994 and July 13, 1994, Governor Roy Romer submitted comprehensive revisions to the Colorado SIP. The carbon monoxide SIP element submittals for Denver and Longmont addressed the outstanding CAA requirements discussed above, as well as other CAA mandates. The July 11, 1994 CO SIP revision for Denver was developed primarily by the Colorado Department of Health's Air Pollution Control Division (APCD), the Colorado Air Quality Control Commission (AQCC), and the Regional Air Quality Council (RAQC), which represents local government and citizen interests. The July 13, 1994 CO SIP revision for Longmont was developed primarily by the APCD, in consultation with the City of Longmont.

The Act requires States to observe certain procedural requirements in developing implementation plans and plan revisions for submission to EPA. Section 110(a)(2) of the Act provides that each implementation plan submitted by a State must be adopted after reasonable notice and public hearing.[1] Section 110(l) of the Act similarly provides that each revision to an implementation plan submitted by a State under the Act must be adopted by such State after reasonable notice and public hearing.

The EPA also must determine whether a submittal is complete and therefore warrants further EPA review and action [see section 110(k)(1) and 57 FR 13565]. The EPA's completeness criteria for SIP submittals are set out at 40 CFR Part 51, Appendix V (1991), as amended by 57 FR 42216 (August 26, 1991). The EPA attempts to make completeness determinations within 60 days of receiving a submission. However, a submittal is deemed complete by operation of law if a completeness determination is not made by EPA within six months after receipt of the submission.

The AQCC held a public hearing on June 16, 1994 to entertain public comment on the implementation plan revisions for Denver and Longmont. Following the public hearing, the SIP revisions were adopted by the AQCC, and forwarded to the Colorado Legislative Council for review. (Under Colorado law, SIP revisions imposing new or revised controls on mobile sources must be reviewed and accepted by the Colorado Legislative Council.) The AQCC held an emergency hearing on July 7, 1994, to address concerns with the Denver SIP raised by the Legislative Council, and on July 11 and July 13, 1994, the SIP revisions were submitted to EPA by the Governor for approval.

The SIP revision was reviewed by EPA to determine completeness shortly after its submittal, in accordance with the completeness criteria set out at 40 CFR Part 51, Appendix V (1991), as amended by 57 FR 42216 (August 26, 1991). The submittal was found to be complete, and a letter dated July 14, 1994 was forwarded to the Governor indicating the completeness of the submittal and the next steps to be taken in the review process. The applicable Clean Air Act requirements and EPA's rationale for its proposed actions are discussed below.

[1] Also, Section 172(c)(7) of the Act requires that plan provisions for nonattainment areas meet the applicable provisions of section 110(a)(2).

Denver

A. Attainment Demonstration and Control Strategies

(1) Attainment Demonstration

As noted, CO nonattainment areas with design values greater than 12.7 ppm were required to submit a demonstration by November 15, 1992, that the plan will provide for attainment by December 31, 1995 for moderate CO nonattainment areas and December 31, 2000 for serious CO nonattainment areas. APCD conducted an attainment demonstration using urban areawide modeling in conjunction with intersection modeling for a modeling region encompassing the Denver nonattainment area.

The CO NAAQS are for 1-hour and 8-hour periods and are not to be exceeded more than once per year. The 1-hour CO NAAQS is 35 ppm (40 mg/m^3) and the 8-hour CO NAAQS is 9 ppm (10 mg/m^3). The demonstration predicted that the highest 8-hour design concentration as of the attainment date will be 8.91 ppm, thus demonstrating attainment of the 8-hour CO NAAQS. No demonstration was required to be carried out for the 1-hour NAAQS, as Denver has not violated this NAAQS since before the 1990 CAAA were enacted. The same strategies which bring the area into attainment with the 8-hour NAAQS will also contribute to reduced 1-hour concentrations. The modeled attainment demonstration is discussed in greater detail below.

(a) Policy Issues: Reclassification to Serious and Applicability of Serious Area SIP Requirements

(i) Reclassification to Serious. During the SIP development process, the RAQC conducted an exhaustive review of control strategies for use in demonstrating attainment of the CO NAAQS by the Clean Air Act-mandated deadline for moderate areas of December 31, 1995. Even with the oxygenated fuels program and an enhanced I/M program in place, the RAQC and APCD determined that a 30% reduction in emissions would still be needed to attain the NAAQS by this date. Any measures would need to be implemented in the 18-month period between SIP adoption (in June 1994) and the attainment date, ruling out many potential strategies with longer implementation horizons. The RAQC considered several aggressive strategies, including a mandatory no-drive day for high emitting vehicles, but was unable to identify a package of strategies that would provide the necessary emission reductions by December 31, 1995.

As a result, the RAQC recommended to the AQCC that the Denver area seek reclassification to serious. If Denver were reclassified to serious, the applicable attainment date would become December 31, 2000 (CAA Section 186(a)(1)). The AQCC adopted this recommendation, and the Governor formally requested reclassification to serious in his July 11, 1994 letter submitting the SIP. As part of this Federal Register document, EPA is proposing to reclassify the Denver-Boulder nonattainment area to serious.

EPA had originally intended to rely upon the authority for reclassification provided by Section 110(k)(6) of the Clean Air Act. This paragraph provides broad authority for EPA to correct previous approvals, disapprovals, designations, and classifications based on new information. However, air quality data collected during calendar year 1995 show that the Denver area experienced two exceedances of the CO NAAQS in 1995 at the CAMP monitor. Because of this, Denver cannot demonstrate attainment of the NAAQS by the statutory December 31, 1995 attainment date for moderate areas, and must be reclassified, by operation of law, to serious. Under Section 186(b)(2)(A), a moderate carbon monoxide nonattainment area must be reclassified as serious by operation of law if the Administrator finds that the area has failed to attain the CO NAAQS. Pursuant to Section 186(b)(2)(B), EPA must publish a document in the Federal Register identifying those areas that failed to attain the NAAQS and the resulting classifications. In this document, EPA is proposing to find that the Denver/Boulder carbon monoxide nonattainment area did not attain the NAAQS by the required attainment date of December 31, 1995, and to revise the area's classification for carbon monoxide in 40 CFR Part 81 from moderate to serious.

(ii) Impacts of Reclassification to Serious. Areas classified as serious are required to attain the CO NAAQS no later than December 31, 2000. In addition, the following additional requirements of CAA Section 187 apply:

Gasoline sold during the winter months must contain a level of oxygen necessary to attain the NAAQS. (CAA Section 187(b)(3))

A mandatory employer-based trip reduction program must be adopted and implemented, unless it can be shown that such a program is not necessary to demonstrate attainment of the NAAQS. (CAA Section 187(b)(2), referencing CAA Section 182(d)(1)(B))

A December 31, 1995 milestone must be identified, and an economic

incentive program must be adopted and implemented if the milestone is not achieved or if the area fails to attain the CO NAAQS by December 31, 2000. (CAA Section 187(d))

Vehicle miles travelled forecasts must be submitted for the period 1996–2000 (submittal of vehicle miles traveled forecasts for 1993–1995 is required for moderate areas). (CAA Section 187(a)(2)(A))

Additional requirements for the content and analysis of transportation plans, programs and projects apply under the EPA/DOT transportation conformity regulations (58 FR 62215, November 24, 1993).

The oxygenated gasoline, VMT forecast, and conformity requirements are discussed elsewhere in this document.

(iii) December 31, 1995 milestone demonstration. CAA Section 187(d) requires areas classified as serious to submit a demonstration no later than March 31, 1996, that the area has achieved CO emission reductions equivalent to the total of the specified annual emission reductions required by December 31, 1995. The Act does not provide further guidance on the form or content of the milestone itself, the specified annual emission reductions, or the nature of the milestone demonstration. EPA has not issued guidance on this matter.

Since the Act does not prescribe a methodology for determining a milestone and EPA has not issued guidance for this purpose, the State has chosen to use its 1995 base case emission inventory as the milestone (Section XII–D of the SIP). The milestone level is 1396 tons per day in the nonattainment area; this level represents progress toward attainment from the 1988 level of 1709 tons per day.

(iv) Employer-based trip reduction program (the ECO program). CAA Section 187(b)(2) requires areas classified as serious to adopt the measures required by Section 182(d)(1). These measures consist of transportation control measures (CAA Section 182(d)(1)(A)) and a mandatory employer-based travel reduction program (commonly known as the Employee Commute Options, or ECO, program) (CAA Section 182(d)(1)(B)). Section 187(b)(2) also provides that, in any area defined as a ''covered area'' under the Clean Fuel Fleet Program requirements of Section 246(a)(2)(B) (the Denver area meets this definition), a SIP may exclude any of the Section 182(d)(1) measures if (1) the SIP includes an explanation of why any measure was not adopted and what emission reduction measure was adopted to provide comparable reduction in emissions, or (2) the SIP contains reasons why such reduction is not necessary to attain the national primary ambient air quality standard for CO. (As a moderate area, Denver was already required by the ''Special Rule for Denver,'' Section 187(a)(2)(B), to address the transportation control measure requirements of Section 182(d)(1)(A). These requirements are discussed in Chapter X of the SIP.)

The SIP demonstrates that no TCMs are necessary to provide for attainment of the NAAQS by December 31, 2000 (attainment demonstration, Tables XII–1 and XII–2). However, several TCMs were adopted as part of the SIP, including transportation management associations to encourage and provide technical support for voluntary employer-based trip reduction activities; financial incentives for subsidized employee transit passes and other travel reduction strategies for downtown Denver employees; transit passes for students at the Auraria campus in downtown Denver; high-occupancy vehicle lanes on Broadway and Lincoln, two major arterials providing access to the central business district; and improved traffic signalization in the central business district and elsewhere in the nonattainment area. Appendix X–A of the SIP also discusses several other TCMs that were adopted and implemented as part of the 1979 and 1982 SIPs for Denver and remain in effect.

Section X.F. of the SIP provides the formal justification for exclusion of the ECO program from the Denver SIP. However, on December 23, 1995, the President signed revisions to the ECO requirements of the Clean Air Act. These revisions amended the Act to make submittal of a SIP revision providing for the ECO program voluntary for areas which are bumped up to a higher classification (and thus, newly made subject to the requirement). Thus, the State would have no longer been required to submit such program, even if EPA had initially interpreted the Act to require this program for Denver.

(b) Technical Evaluation of Attainment Demonstration

EPA is proposing to approve the State's attainment demonstration for Denver. EPA has determined that the State correctly applied national guidance in conducting modeling of the entire region and of six intersections that could potentially cause violations of the CO NAAQS. In addition, the State complied with a Region VIII request to conduct modeling of downtown intersections above and beyond the six required by national guidance. However, due to the factors described below, the model could not be properly applied to two high-traffic downtown intersections: Speer/Auraria and Broadway/Colfax. Model predictions at these two sites were affected by uncertainties in meteorological and motor vehicle emissions inputs. In addition, the modeled predictions of high ambient values at these intersections were not supported by saturation monitoring data obtained at the same locations. Thus, the attainment demonstration is based on modeled and monitored values at a third downtown intersection, CAMP, which has historically recorded the highest CO concentrations in the Denver metro area. These issues are discussed in greater detail below.

A variety of specialized models were used to model the Denver area carbon monoxide concentrations in accordance with EPA guidance. The Urban Airshed Model (UAM) was used to simulate regional concentrations during two historical episodes when very high carbon monoxide levels occurred. During these same episodes the CAL3QHC model was used to simulate concentrations from local streets and roadways. The outputs from both models were added together so that total predicted concentrations could be compared with values actually measured at the monitoring sites during these episodes. These comparisons determine if the modeling meets the performance criteria prescribed in the UAM guidance document, and in the modeling protocol. For both episodes there was a tendency for the UAM/CAL3QHC model to underpredict concentrations. However, the degree of underprediction was within the limits specified in EPA UAM Guidance documents, and in the modeling protocol.

The validated UAM/CAL3QHC model was then applied in the attainment year (2000) to determine whether proposed control strategies are sufficient to meet the 8-hour ambient air quality standard (9.0 ppm). The same meteorological conditions used in the model validation runs were used in the 2000 model runs. However, the 2000 runs were modeled with revised emission input files to examine the benefits of the various control strategies. The 2000 attainment runs showed that the control strategies in the SIP are sufficient to reduce carbon monoxide concentrations to less than 9.0 ppm at all locations in the nonattainment area.

The Denver CO modeling protocol was approved by EPA Region VIII in

May 1992. Specific intersections to be modeled were not identified in the protocol. The State showed attainment on each of the six highest ranked intersections selected for modeling, following screening criteria contained in ''Guideline for Modeling CO from Roadway Intersections'', EPA–454/R–92–005. The State subsequently found that the six busiest intersections for traffic congestion were located in the suburban areas, where background air quality levels are relatively low. Application of CAL3QHC at these six locations, combined with UAM predicted background levels, showed the year 2000 concentrations at levels well within the CO NAAQS. The Region requested the State to model an additional intersection in the central business district, to ensure that control strategies provide for attainment at hot spot locations in the urban core area, not just at suburban locations exposed to significantly lower background concentrations.

The State performed preliminary CAL3QHC modeling at three additional intersections in the Downtown area: Speer & Auraria; Broadway & Colfax; and Broadway & Champa. These preliminary 1995 results showed predicted concentrations at Speer/Auraria and Broadway/Colfax up to 6 ppm higher than concentrations modeled at the CAMP monitor (Broadway & Champa). Because of uncertainties related to the validity of meteorological inputs used in the model, the State opted not to include the CAL3QHC modeling results for the two higher intersections in the current SIP, deferring consideration of these locations until additional saturation monitoring studies could be conducted at these intersections. The State selected Broadway and Champa as the intersection to use in the SIP attainment demonstration because the on-site air quality and meteorology monitoring data available at this location provided more confidence in the results, i.e., produced modelled concentrations that were in good agreement with concentrations actually monitored at the site. There are significant and unique micro-meteorological effects influencing each of the three central business district intersections, including: high-rise office buildings, channeling of the wind down ''urban street canyons'', and urban heat island effects. Since the Diagnostic Wind Model (DWM) used with UAM does not include any of these effects, the State did not consider the meteorological outputs from DWM appropriate for use in microscale modeling.

The State's intersection analysis is consistent with national policy and other recent UAM/CAL3QHC modeling applications. Additional information on the attainment demonstration modeling is included in the Technical Support Document for this action.

(2) Control Strategies

Section 172(c)(1) requires the plans for all nonattainment areas to provide for the implementation of RACM (including RACT) as expeditiously as practicable and to provide for attainment of the NAAQS. The EPA interprets this requirement to impose a duty on all nonattainment areas to consider the available control measures, and to adopt and implement such measures as are reasonably available for implementation in the area and necessary for attainment of the NAAQS as components of the area's attainment demonstration. The EPA has reviewed the State's explanation and associated documentation and concluded that it adequately justifies the control measures to be implemented. EPA is proposing to approve several of the control strategies. The exact nature of EPA's proposed approvals is discussed in more detail below and in the Technical Support Document for today's action.

The Denver CO SIP takes credit for several control programs in the attainment demonstration. Those identified in Chapter V of the SIP as ''baseline strategies'' are measures which were in existence at the time of CO SIP development, and for which no further State regulatory action was required. EPA is not taking action on these control strategies through this SIP revision, as these are strategies which have been adopted through previous SIP revisions and have been or are being acted on in other Federal Register documents. Those identified as ''additional control strategies'' are measures which were newly-considered and adopted for the attainment demonstration, and which are being acted on in this SIP revision.

The baseline strategies include the Federal motor vehicle control program, the 2.7% oxygenated fuels program (approved in the Federal Register on July 25, 1994 (59 FR 37698)), the Enhanced inspection and maintenance (I/M) program (conditionally approved in the Federal Register on November 8, 1994 (59 FR 55584)), various transportation system improvements, and the woodburning control measures adopted as part of the Denver PM10 SIP (approved in the Federal Register on July 25, 1994 (59 FR 37698)).

In addition, Section 246 of the Clean Air Act requires that the State adopt and implement the Clean Fuels Fleet Program, an alternative fuels program for certain commercial and governmental fleet operations. AQCC Regulation 17, the Clean Fuels Fleet Program regulation, was adopted by the AQCC on May 5, 1994, and submitted with the Denver CO SIP. (The full Clean Fuels Fleet Program SIP was submitted to EPA on October 17, 1994.) A wide variety of non-mandated alternative fuels programs are also underway in the Denver area. No credit is taken for Regulation 17 or any of the other programs in the attainment demonstration, and EPA will act on the Clean Fuels Fleet Program in the Federal Register at a later date.

Several additional control strategies have been formally incorporated into or committed to in the Denver CO SIP to provide for attainment of the CO NAAQS by December 31, 2000. These measures are described in Chapter VI of the SIP and are discussed below.

(a) 3.1% oxygenated fuels program. In the CO SIP, the State made a commitment, which has since been met, to implement and adopt a 3.1% oxygenated fuels program, providing additional benefit over the 2.7% program already required of the area by Section 211(m) of the Act. The program is being implemented in two phases. In the winter of 1994–95, a ''maximum blending'' program took effect, which requires gasoline suppliers using methyl tert-butyl ether as an oxygenate to blend at the 2.7% oxygen level (the maximum allowed by Federal regulations), and suppliers using ethanol as an oxygenate to blend at the 3.5% oxygen level (also the maximum allowed by Federal regulations). The market share of ethanol in the Denver area has exceeded 50% in recent years, and this approach is expected to result in at least a 3.1% oxygen content during each winter season. If the maximum blending approach should fail to provide for at least a 3.1% oxygen content, the SIP provides that in subsequent winter seasons an averaging program, pursuant to EPA guidance for such programs, will take effect.

AQCC Regulation 13 governs the oxygenated fuels program. The SIP committed to revise this regulation in two steps. Reg 13 was revised to incorporate the maximum blending approach for the winter of 1994–95 by the AQCC on July 19, 1994. Reg 13 was revised to incorporate the more complex 3.1% averaging program on October 20, 1994. Both sets of regulation revisions were submitted by the Governor for EPA approval on September 29, 1995. The

September 29, 1995 submittal was determined complete on November 30, 1995.

(b) Increased I/M failure rate for pre-1982 vehicles. The SIP includes a commitment, which has since been met, to revise Regulation 11, which governs the I/M program, to incorporate more stringent emissions cutpoints which will increase the failure rate for pre-1982 vehicles from the current 14–26% to approximately 40%. Pre-1982 vehicles have less advanced emission control system technology, resulting in higher CO emission levels, and the more stringent cutpoints for these vehicles will result in the identification and repair of a greater number of high-emitting vehicles than are captured by the present I/M program (an increase of approximately 70,000 vehicles per year). These regulation revisions were adopted by the AQCC on September 22, 1994, and submitted by the Governor for EPA approval on September 29, 1995. The September 29, 1995 submittal was determined complete on November 30, 1995.

(c) Prohibition on the re-registration of abandoned and impounded pre-1982 vehicles sold at auction. This element of the SIP requires local governments in the Denver area to modify their ordinances or procedures for disposing of pre-1982 abandoned and impounded vehicles to prohibit purchasers from obtaining any form of title to the vehicles. These vehicles may be sold for scrappage or dismantling only. This measure will accelerate the normal rate of removal of vehicles of this age from the fleet, by preventing up to 5,000 vehicles of this type from being re-registered. Elimination of this many pre-1982 vehicles could reduce regional CO emissions by up to 5 tons per day. However, because of the difficulty of defining a concise emission reduction, the State does not take credit for this strategy in the attainment demonstration.

B. Transportation Control Measures

Section 187(a)(2)(B) (Special Rule for Denver) requires the State to submit a SIP revision that includes the TCMs as required in Section 182(d)(1)(A) of the Act, for the purpose of reducing CO emissions. The SIP may exclude any of the Section 182(d)(1)(A) measures if 1) the SIP includes an explanation of why any measure was not adopted and what emission reduction measure was adopted to provide comparable reduction in emissions, or 2) the SIP contains reasons why such reduction is not necessary to attain the national primary ambient air quality standard for CO.

The TCM SIP revision is contained in Chapter X of the Denver CO SIP. The TCMs adopted as part of the SIP are listed below. See the Technical Support Document for today's document and the SIP itself for a more detailed description of these measures.

(1) Employer-based transportation emission management programs promoted and encouraged by transportation management associations and financial incentives.

(2) Auraria transit pass.

(3) Conversion of Broadway/Lincoln Bus Lanes to Bus/HOV.

(4) Improved Traffic Signalization.

(5) Other Measures.

Appendix X–A contains the State's assessment of the measures listed in Section 108(f), including a comprehensive description of strategies already in place in Denver and the newly-adopted measures. Several TCMs have already been adopted as part of the SIP in previous ozone and CO SIP revisions, and have been approved by EPA (45 FR 51199, August 1, 1980, and 48 FR 55284, December 12, 1983). Appendix X–A also describes projects and programs which are not being included in the SIP but nevertheless provide some emission reduction benefit.

EPA is proposing to approve this element of the Denver CO SIP. The SIP satisfies the requirement of Section 187(a)(2)(B) to either include the TCMs or provide a justification for not including them. The attainment demonstration for the SIP does not include credit for any of the TCMs; however, the above measures were adopted as enforceable provisions of the SIP.

C. Vehicle Miles Traveled Forecasting and Tracking

Section 187(a)(2)(A) of the Clean Air Act Amendments of 1990 required EPA, in consultation with the U.S. Department of Transportation (DOT), to develop guidance for states to use in complying with the VMT forecasting and tracking provisions of Section 187. A Notice of Availability for the resulting *Section 187 VMT Forecasting and Tracking Guidance* was published in the Federal Register on March 19, 1992. Section 187(a)(2)(A) requires Denver to submit a SIP revision providing for a VMT forecasting and tracking program, and contingency measures for implementation in the event that a VMT forecast is exceeded. The specific requirements are discussed in detail in the Technical Support Document for today's action.

The State of Colorado has submitted a SIP revision to EPA in order to satisfy the requirements of Section 187(a)(2)(A) and Section 187(a)(3). In order to gain approval, the State submittal must provide for each of the following mandatory elements: (1) a forecast of VMT in the non-attainment area for each year prior to the attainment year; (2) a provision for annual updates of the forecasts along with a provision for annual reports describing the extent to which the forecasts proved to be accurate; these reports shall provide estimates of actual VMT in each year for which a forecast was required; (3) adopted and enforceable contingency measures to be implemented without further action by the State or the Administrator if actual annual VMT or an updated forecast exceeds the most recent prior forecast or if the area fails to attain the CO NAAQS by the attainment date.

(1) VMT Forecasts

Section 187(a)(2)(A) requires that the State include in its SIP submittal a forecast of VMT in the non-attainment area for each year before the year in which the SIP projects the National Ambient Air Quality Standard for CO will be attained. The forecasts are to be based on guidance developed by EPA in consultation with DOT, i.e., the *Section 187 VMT Forecasting and Tracking Guidance.* Table XIV–2 of the SIP contains the required forecasts of annual VMT for the years 1993–2001.

(2) Annual VMT Updates/Reports

Section 187(a)(2)(A) specifies that the SIP revision provide for annual updates of the VMT forecasts and annual reports that describe the accuracy of the forecasts and that provide estimates of actual VMT in each year for which a forecast was required. The *Section 187 VMT Forecasting and Tracking Guidance* specifies that annual reports should be submitted to EPA by September 30 of the year following the year for which the VMT estimate is made. The SIP commits to the submission of these annual reports and identifies responsibilities among the various transportation agencies in Denver to develop the reports.

(3) Contingency Measures

Section 187(a)(3) specifies that the State, in its SIP revision, adopt specific, enforceable contingency measures to be implemented if the annual estimate of actual VMT or a subsequent VMT forecast exceeds the most recent prior forecast of VMT or if the area fails to attain the CO NAAQS by the attainment date. Implementation of the identified contingency measures must not require further rulemaking activities by the

State or EPA. Certain actions, such as notification of sources, would probably be needed before a measure could be implemented effectively. The State has met this requirement, as discussed in Section D. below. The State of Colorado has submitted a SIP revision implementing each of the required elements required by Section 187(a)(2)(A) and Section 187(a)(3) of the CAAA.

D. Contingency Measures

The Clean Air Act requires each CO nonattainment area with a design value above 12.7 ppm at the time of classification to adopt contingency measures that will take effect without further action by the State or EPA upon a determination by EPA that an area failed to make reasonable further progress or to attain the standards, as described in § 172(c)(9), or that actual or forecasted VMT exceeded a previous forecast. Section 187(a)(3) requires the State to submit a SIP revision containing contingency measures no later than November 15, 1992. The State submitted these measures as part of the Denver CO SIP on July 11, 1994.

States may implement contingency measures early to obtain additional emission reductions, without being required to adopt replacement contingency measures to put in place should one of the triggering events for implementation of contingency measures occur. This policy is described in a memorandum from Tom Helms, Chief of the OAQPS Ozone Policy and Strategies Group entitled ''Early Implementation of Contingency Measures for Ozone and Carbon Monoxide Nonattainment Areas,'' August 13, 1993.

As noted above, the State did not take credit in the attainment demonstration for the TCMs adopted to meet the requirements of Section 187(a)(2)(B). Because these measures are surplus to the reductions needed for attainment, the State has adopted these as the required contingency measures as well. The Denver region is proceeding with early implementation of these measures to obtain the additional emission reductions they provide.

If a triggering event for contingency measures occurs, EPA will review the status of implementation of the TCMs adopted in Chapter X of the SIP. Each of the TCMs must be fully implemented in order to satisy the contingency measures requirements of Sections 172 and 187. In addition, the EPA/DOT transportation conformity regulation (58 FR 62235, November 24, 1993) requires DRCOG and USDOT to demonstrate that SIP TCMs are being implemented or are on schedule for implementation before making a conformity determination for transportation plans or TIPs. This provides an extra degree of assurance that the contingency measures will be implemented if needed.

Section XIII.C. of the SIP defines the target emissions reduction level for contingency measures. Based on average projected annual VMT growth between 1995 and 2000 and the modeled fleet emission factors for those years, the State determined that minimum emission reductions of 26 tons per day in 1995 and 16 tons per day in 2000 represented the minimum emission reduction levels for contingency measures pursuant to EPA guidance. The TCMs, when fully implemented, are projected to produce an emission reduction of 34 tons per day in the year 2000. The emission reductions would be higher in earlier years, since the baseline fleet emission factors to which the contingency measure effectiveness would be applied are higher. Thus, the submittal satisfies EPA's minimum criteria for contingency measure effectiveness.

E. Mobile Source Emissions Budgets and Transportation Conformity

Section 176(c)(1) of the Act directs that no department, agency, or instrumentality of the federal government may permit any activity that does not conform to a SIP. Section 176(c)(2) further specifies that federally funded transportation improvement programs (TIPs), regional transportation plans, and projects must conform to the SIP in order to be adopted by the metropolitan planning organization. EPA and DOT promulgated implementing regulations for this CAA provision on November 24, 1993 (58 FR 62235).

One key provision of the conformity regulations requires a demonstration that emissions from the transportation plan and TIP are consistent with the emissions budget in the SIP (Sections 93.118 and 93.119 of the conformity rule). The emissions budget is defined as the level of mobile source emissions relied upon in the attainment and/or maintenance demonstration to achieve compliance with the NAAQS in the nonattainment area. The rule's requirements and EPA's policy on emissions budgets are found in the Preamble to the transportation conformity rule (58 FR 62193–96) and in the sections of the rule referenced above. The SIP defines emissions budgets for the 1995 milestone year and the 2000 attainment year.

The 1995 budget is consistent with the mobile source emissions estimate for the milestone year and is 1125 tons per day in the nonattainment area. This budget no longer applies for conformity, since that date has passed. For the year 2000, the SIP includes modeling for scenarios with and without TCMs. The RAQC recommended that the AQCC adopt the emissions budget for the scenario without TCMs as the budget to be used for conformity (825 tons per day in the nonattainment area). However, the AQCC adopted (and the Governor submitted) an emission budget of 808 tons per day in the nonattainment area. This lower budget reflected some (not all) of the emissions reductions associated with the implementation of the TCMs. The AQCC felt that this lower budget would provide a margin of safety for attainment and would provide an extra incentive (through the conformity requirements) for implementation of the TCMs.

Subsequent to submittal of the SIP, DRCOG completed an initial conformity analysis for the 2015 transportation plan and the 1995–2000 TIP, and found that the plan and TIP could not conform to the lower budget adopted by the AQCC and submitted to EPA. In response, the RAQC adopted a resolution requesting that the AQCC revise the SIP to raise the emission budget to the attainment level of 825 tons per day. The AQCC adopted this SIP revision after a public hearing on February 16, 1995, and the Governor submitted this SIP revision on July 18, 1995.

The Governor's July 18, 1995 letter withdraws the 808 ton per day emission budget submitted on July 11, 1994. This leaves the default budget of 825 tons per day from the attainment demonstration as the applicable budget under EPA's conformity rule. Since EPA is proposing to approve the attainment demonstration, the 825 ton per day budget that the attainment demonstration is based on would be approved by default, and no separate action is necessary on the July 18, 1995 submittal of this budget.

Section 93.106(b) of the conformity rule requires that the transportation plans in moderate nonattainment areas reclassified to serious meet certain content and analysis requirements. These new requirements would affect plans adopted two years after reclassification to serious. Once EPA reclassifies the Denver area to serious, these requirements will take effect two years thereafter. DRCOG's transportation planning methodologies already meet many of these requirements.

Longmont

A. Background of Sip Revision

Pursuant to the requirements of the 1990 Clean Air Act Amendments, each State was required to identify its nonattainment areas and submit descriptions of these areas for EPA promulgation in 40 CFR Part 81. Longmont had been designated as unclassifiable/attainment prior to passage of the 1990 Amendments. However, a special monitoring study in 1988–89 recorded an exceedance of the NAAQS in Longmont. (This study is described in Chapter II of the Longmont SIP.) As a result, EPA Region VIII recommended that the Governor designate this area nonattainment in a letter dated January 15, 1991. In a letter dated March 15, 1991, Governor Roy Romer submitted a request that Longmont be designated a moderate nonattainment area, and submitted boundaries for the new area. The designation, classification and boundaries were promulgated by EPA in the Federal Register on November 6, 1991 (56 FR 56733).

Since this area had never had a SIP, EPA interpreted Section 172 of the Act to require an attainment demonstration for Longmont. As a moderate area, the applicable attainment date for Longmont is December 31, 1995. Contingency measures under Section 172(b)(9) were also required. On January 15, 1993, EPA made a formal finding that the State had failed to submit these SIP revisions for Longmont.

On July 13, 1994, Governor Roy Romer submitted comprehensive revisions to the Colorado SIP. The carbon monoxide SIP element submittal for Longmont addressed the outstanding CAA requirements discussed above, as well as other CAA mandates. EPA found this SIP element complete on July 14, 1994. The CO SIP revision for Longmont was developed primarily by APCD, in consultation with the City of Longmont. The SIP development process is discussed in Chapter I of the SIP.

Throughout the remainder of this Federal Register document, references are made to the ''Longmont area.'' This is a matter of convenience; these references apply to the Longmont CO nonattainment area as defined in 40 CFR Part 81 unless otherwise noted.

B. Attainment Demonstration and Control Strategies: Longmont

(1) Attainment Demonstration

A different approach was used for demonstrating attainment in Longmont than the methodology used in Denver. Originally, the State planned to develop the attainment demonstration for Longmont as part of the modeling for Denver. However, it was discovered that the ambient conditions which led to exceedances of the CO NAAQS in Denver were not directly applicable to Longmont. After reviewing the results of the 1988–89 special monitoring studies, which suggested that exceedances occur due to emissions on a neighborhood scale, and in consideration of Longmont's small size and low traffic counts relative to conditions in Denver, EPA concluded that the complex UAM/CAL3QHC modeling methodology used in Denver was not necessary for demonstrating attainment in Longmont. EPA recommended that a simple rollforward analysis, similar to that used in attainment demonstrations for Colorado's smaller PM10 nonattainment areas, be used for Longmont. This decision is documented in a July 26, 1993 letter from EPA to APCD.

The methodology used and the results are presented in Chapter IV of the SIP. The SIP projects a second maximum concentration of 6.97 ppm at the end of 1995, well below the 9.0 ppm NAAQS.

(2) Control Strategies

Section 172(c)(1) of the Act requires the plans for all nonattainment areas to provide for the implementation of RACM (including RACT) as expeditiously as practicable and to provide for attainment of the NAAQS. EPA interprets this requirement to impose a duty on all nonattainment areas to consider the available control measures, and to adopt and implement such measures as are reasonably available and necessary for attainment of the NAAQS as components of the area's attainment demonstration. EPA has reviewed the State's explanation and associated documentation and concluded that it adequately justifies the control measures being implemented.

The Longmont CO SIP takes credit for several control programs in the attainment demonstration. These control strategies, identified in Table III.3 and discussed in Chapter V of the SIP, are measures which were in existence at the time of CO SIP development, and for which no further State regulatory action was required. EPA is not taking action on these control strategies in this Federal Register document, as these are strategies which have been adopted through previous SIP revisions and have been or are being acted on in other Federal Register documents. The attainment demonstration does not take credit for any newly-adopted control strategies, nor are any such strategies included in the SIP. In addition, Chapter V discusses several other activities underway in the Longmont area that have emission reduction benefits. However, these activities are not identified as control strategies and are not reflected in the 1995 attainment emission inventory, and thus, EPA is not incorporating these measures into the SIP.

The control strategies relied upon for the Longmont attainment demonstration include the Federal motor vehicle control program, the 2.7% oxygenated fuels program (approved in the Federal Register on July 25, 1994 (59 FR 37698)), the enhanced inspection and maintenance (I/M) program (conditionally approved in the Federal Register on November 8, 1994 (59 FR 55594)), various ongoing travel reduction strategies and transportation system improvements, and woodburning control measures from the Denver PM10 SIP (the woodburning program was approved in the Federal Register on July 25, 1995 (59 FR 37698)).

The package of strategies incorporated in the attainment demonstration is expected to reduce emisssions from 55.070 tons per day in 1988 to 37.292 tons per day in 1995, for an overall reduction of approximately 32%. The strategies result in a 1995 projected second maximum concentration of 6.97 ppm.

C. Contingency Measures: Longmont

EPA's requirements for contingency measures are described above. Unlike Denver, Longmont is not subject to the CAA Section 187(a)(2)(A) requirement for a VMT forecasting and tracking program, and thus is not required to implement contingency measures in the event that a VMT forecast is exceeded. Contingency measures for Longmont were submitted as part of the July 13, 1994 SIP.

The 3.1% oxygenated fuels program, adopted as part of the Denver CO SIP, has been adopted as the contingency measure for Longmont. This measure is being implemented in the entire six-county Denver metropolitan area as required by the Clean Air Act, and thus is being implemented in Longmont, even though it is not credited in the attainment demonstration. EPA considers this to be early implementation of the contingency measure, as provided for in the August 13, 1993 Tom Helms memorandum referenced above.

Section V.C. of the SIP defines the target emissions reduction level for contingency measures. VMT growth in Longmont was estimated at 3.1% per

year, which equates to CO emissions growth of 0.92 tons per year. The 3.1% oxygenated fuels program gives Longmont an additional incremental emission reduction over the 2.7% program of 1.01 tons per year, which exceeds the minimum emission reduction level. Thus, EPA's minimum requirements for contingency measures are satisfied by the State's submittal.

II. Implications of This Action

In today's action, EPA is proposing to approve SIP revisions submitted by the Governor on July 11, 1994, July 13, 1994, and September 29, 1995. Specifically, EPA is proposing to (1) approve the July 11, 1994 attainment demonstration, VMT tracking and forecasting program, TCM, and contingency measures submittals for Denver; (2) approve the July 13, 1994 attainment demonstration and contingency measures submittals for Longmont; and (3) approve the control strategies for Denver, including the September 29, 1995 submittal of revisions to Regulations 11 and 13 (I/M and oxygenated fuels).

In this document, EPA is also proposing to find that the Denver/Boulder carbon monoxide nonattainment area did not attain the NAAQS by the required attainment date of December 31, 1995, and to revise the area's classification for carbon monoxide in 40 CFR Part 81 from moderate to serious. This proposed finding is based on air quality data revealing more than one exceedance of the CO NAAQS during calendar year 1995, resulting in a design value higher than the NAAQS for the period 1994–95. By action dated December 20, 1994, the EPA Administrator delegated to the Regional Administrators the authority to determine whether CO nonattainment areas attained the NAAQS, and to reclassify those that did not.

III. Request for Public Comments

EPA is requesting comments on all aspects of today's proposal. As indicated at the outset of this document, EPA will consider any comments received by August 8, 1996.

IV. Executive Order (EO) 12866

Under EO 12866, 58 FR 51735 (October 4, 1993), EPA is required to determine whether regulatory actions are significant and therefore should be subject to OMB review, economic analysis, and the requirements of the EO. The EO defines a ''significant regulatory action'' as one that is likely to result in a rule that may meet at least one of the four criteria identified in section 3(f) of the EO, including, under paragraph (1), that the rule may ''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.''

The SIP-related actions proposed today have been classified as Table 3 actions for signature by the Regional Administrator under the procedures published in the Federal Register on January 19, 1989 (54 FR 2214–2225), as revised by a July 10, 1995 memorandum from Mary Nichols, Assistant Administrator for Air and Radiation. The Office of Management and Budget has exempted these regulatory actions from EO 12866 review.

Likewise, EPA has determined that the finding of failure to attain proposed today would result in none of the effects identified in section 3(f) of the EO. Under Section 186(b)(2) of the Clean Air Act, findings of failure to attain and reclassification of nonattainment areas are based upon air quality considerations and must occur by operation of law in light of certain air quality conditions. They do not, in and of themselves, impose any new requirements on any sectors of the economy. In addition, because the statutory requirements are clearly defined with respect to the differently classified areas, and because those requirements are automatically triggered by classifications that, in turn, are triggered by air quality values, findings of failure to attain and reclassification cannot be said to impose a materially adverse impact on State, local, or tribal governments or communities.

V. Regulatory Flexibility

Under the Regulatory Flexibility Act, 5 U.S.C. section 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. sections 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 jurisidiction over populations that are less than 50,000.

SIP revision 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 process does not impose any new requirements, EPA certifies that this proposed rule would 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 actions. 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, 256–266 (S. Ct. 1976); 42 U.S.C. section 7410(a)(2).

As discussed in section IV. of this document, findings of failure to attain and reclassification of nonattainment areas under Section 186(b)(2) of the CAA do not, in and of themselves, create any new requirements. Therefore, I certify that today's proposal does not have a significant impact on small entities.

VI. Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate, or to the private sector, of $100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the SIP approval actions proposed today do not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local or tribal governments in the aggregate, or to the private sector. These Federal actions approve pre-existing requirements under State or local law, and impose no new Federal requirements. Accordingly, no additional costs to State, local or tribal governments, or to the private sector, result from these actions.

Likewise, EPA believes, as discussed in section IV of this document, that the proposed finding of failure to attain and reclassification to serious are factual determinations based upon air quality data and must occur by operation of law and, hence, do not impose any federal intergovernmental mandate, as defined in section 101 of the Unfunded Mandates Act.

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Intergovernmental relations, Reporting recordkeeping requirements.

40 CFR Part 81

Air pollution control.

Authority: U.S.C. 7401–7671q.

Dated: June 24, 1996.

Jack W. McGraw,

Acting Regional Administrator.

[FR Doc. 96–17319 Filed 7–8–96; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 55

[FRL–5534–7]

Outer Continental Shelf Air Regulations; Consistency Update for California

AGENCY: Environmental Protection Agency (''EPA'').

ACTION: Notice of proposed rulemaking; consistency update.

SUMMARY: EPA is proposing to update a portion of the Outer Continental Shelf (''OCS'') Air Regulations. Requirements applying to OCS sources located within 25 miles of states' seaward boundaries must be updated periodically to remain consistent with the requirements of the corresponding onshore area (''COA''), as mandated by section 328(a)(1) of the Clean Air Act (''the Act''), the Clean Air Act Amendments of 1990. The portion of the OCS air regulations that is being updated pertains to the requirements for OCS sources for which the South Coast Air Quality Management District (South Coast AQMD) and the Ventura County Air Pollution Control District (Ventura County APCD) are the designated COAs. The OCS requirements for the above Districts, contained in the Technical Support Document, are proposed to be incorporated by reference into the Code of Federal Regulations and are listed in the appendix to the OCS air regulations. Proposed changes to the existing requirements are discussed below.

DATES: Comments on the proposed update must be received on or before August 8, 1996.

ADDRESSES: Comments must be mailed (in duplicate if possible) to: EPA Air Docket (A–5), Attn: Docket No. A–93–16 Section XII, Environmental Protection Agency, Air and Toxics Division, Region 9, 75 Hawthorne St., San Francisco, CA 94105.

Docket: Supporting information used in developing the proposed notice and copies of the documents EPA is proposing to incorporate by reference are contained in Docket No. A–93–16 Section XII. This docket is available for public inspection and copying Monday–Friday during regular business hours at the following locations:

EPA Air Docket (A–5), Attn: Docket No. A–93–16 Section XII, Environmental Protection Agency, Air and Toxics Division, Region 9, 75 Hawthorne St., San Francisco, CA 94105.

EPA Air Docket (LE–131), Attn: Air Docket No. A–93–16 Section XII, Environmental Protection Agency, 401 M Street SW, Room M–1500, Washington, DC 20460. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Christine Vineyard, Air and Toxics Division (A–5–3), U.S. EPA Region 9, 75 Hawthorne Street, San Francisco, CA 94105, (415) 744–1197.

SUPPLEMENTARY INFORMATION:

Background

On September 4, 1992, EPA promulgated 40 CFR part 55[1], which established requirements to control air pollution from OCS sources in order to attain and maintain federal and state ambient air quality standards and to comply with the provisions of part C of title I of the Act. Part 55 applies to all OCS sources offshore of the States except those located in the Gulf of Mexico west of 87.5 degrees longitude. Section 328 of the Act requires that for such sources located within 25 miles of a state's seaward boundary, the requirements shall be the same as would be applicable if the sources were located in the COA. Because the OCS requirements are based on onshore requirements, and onshore requirements may change, section 328(a)(1) requires that EPA update the OCS requirements as necessary to maintain consistency with onshore requirements.

Pursuant to § 55.12 of the OCS rule, consistency reviews will occur (1) at least annually; (2) upon receipt of a Notice of Intent under § 55.4; or (3) when a state or local agency submits a rule to EPA to be considered for incorporation by reference in part 55. This notice of proposed rulemaking is being promulgated in response to the submittal of rules by two local air pollution control agencies. Public comments received in writing within 30 days of publication of this notice will be considered by EPA before publishing a notice of final rulemaking.

Section 328(a) of the Act requires that EPA establish requirements to control air pollution from OCS sources located within 25 miles of states' seaward boundaries that are the same as onshore requirements. To comply with this statutory mandate, EPA must incorporate applicable onshore rules into part 55 as they exist onshore. This limits EPA's flexibility in deciding which requirements will be incorporated into part 55 and prevents EPA from making substantive changes to the requirements it incorporates. As a result, EPA may be incorporating rules into part 55 that do not conform to all of EPA's state implementation plan (SIP) guidance or certain requirements of the Act. Consistency updates may result in the inclusion of state or local rules or regulations into part 55, even though the same rules may ultimately be disapproved for inclusion as part of the SIP. Inclusion in the OCS rule does not imply that a rule meets the requirements of the Act for SIP approval, nor does it imply that the rule will be approved by EPA for inclusion in the SIP.

EPA Evaluation and Proposed Action

In updating 40 CFR part 55, EPA reviewed the rules submitted for inclusion in part 55 to ensure that they are rationally related to the attainment or maintenance of federal or state ambient air quality standards or part C of title I of the Act, that they are not designed expressly to prevent exploration and development of the OCS and that they are applicable to OCS sources. 40 CFR 55.1. EPA has also evaluated the rules to ensure they are not arbitrary or capricious. 40 CFR 55.12 (e). In addition, EPA has excluded administrative or procedural rules,[2] and requirements that regulate toxics which are not related to the attainment and maintenance of federal and state ambient air quality standards.

A. After review of the rules submitted by South Coast AQMD against the criteria set forth above and in 40 CFR part 55, EPA is proposing to make the following rules applicable to OCS sources for which the South Coast AQMD is designated as the COA.

1. *The following rules were submitted as revisions to existing requirements:*

Rule 102 Definition of Terms (Adopted 11/17/95)

[1] The reader may refer to the Notice of Proposed Rulemaking, December 5, 1991 (56 FR 63774), and the preamble to the final rule promulgated September 4, 1992 (57 FR 40792) for further background and information on the OCS regulations.

[2] After delegation, each COA will use its administrative and procedural rules as onshore. In those instances where EPA does not delegate authority to implement and enforce part 55, EPA will use its own administrative and procedural requirements to implement the substantive requirements. 40 CFR 55.14 (c)(4).

Rule 212 Standards for Approving Permits and Proposed Amended Regulation XIII—New Source Review (Adopted 12/7/95) except (e)
Rule 301 Permit Fees (Adopted 10/13/95)
Rule 431.1 Sulfur Content of Gaseous Fuels (Adopted 11/17/95)
Rule 701 Air Pollution Emergency Contingency Actions (Renamed) (Adopted 9/8/95)
Rule 1134 Emissions of Oxides of Nitrogen from Stationary Gas Turbines (Adopted 12/7/95)
Rule 1149 Storage Tank Degassing (Adopted 7/14/95)
Rule 1301 General (Adopted 12/7/95)
Rule 1302 Definitions (Adopted 12/7/95)
Rule 1303 Requirements (Adopted 12/7/95)
Rule 1304 Exemptions (Adopted 12/7/95)
Rule 1306 Emission Calculations (Adopted 12/7/95)
Rule 1313 Permit to Operate (Adopted 12/7/95)
Rule 1610 Old-Vehicle Scrapping (Adopted 10/13/95)
Rule 1612 Credits for Clean On-Road Vehicles (Adopted 9/8/95)
Rule 1620 Credits for Clean Off-Road Mobile Equipment (Adopted 9/8/95)
Rule 2000 General (Adopted 12/7/95)
Rule 2001 Applicability (Adopted 12/7/95)
Rule 2002 Allocations for Oxides of Nitrogen (NOx) and Oxides of Sulfur (SOx) (Adopted 12/7/95)
Rule 2004 Requirements (Adopted 12/7/95)
Rule 2005 New Source Review for RECLAIM (Adopted 12/7/95) except (i)
Rule 2006 Permits (Adopted 12/7/95)
Rule 2007 Trading Requirements (Adopted 12/7/95)
Rule 2015 Backstop Provisions (Adopted 12/7/95) except (b)(1)(G) and (b)(3)(B)
Appendix A Volume IV—(Protocol for oxides of sulfur) (Adopted 9/8/95)
Appendix A Volume V—(Protocol for oxides of nitrogen) (Adopted 9/8/95)
Rule 2100 Registration of Portable Equipment (adopted 12/8/95)

2. *The following rule was submitted to be added as a new requirement:*

Rule 118 Emergencies (Adopted 12/8/95)

3. *The following rules were submitted but will not be included because they are Administrative and/or Procedural:*

Rule 301.2 Annual Operating Permit Fee-Reduced Penalty for Underpayment (Adopted 8/11/95)
Rule 310 Amnesty for Unpermitted Equipment (Adopted 10/13/95)
Rule 1309 Emission Reduction Credits (Adopted 12/7/95)
Rule 1309.1 Priority Reserve (Adopted 12/7/95)
Rule 1310 Analysis and Reporting (Adopted 12/7/95)
Rule 1501 Work Trip Reduction Plans (Adopted 12/8/95)
Rule 1501.1 Alternatives to Work Trip Reduction Plans (Adopted 12/8/95)
Rule 2202 On-Road Motor Vehicle Mitigation Options (Adopted 12/8/95)

4. *The following rules were submitted but will not be included until the District submits the resolution for these rules:*

Rule 2011 Requirements for Monitoring, Reporting, and Recordkeeping for Oxides of Sulfur (SOx) Emissions (Adopted 12/7/95)
Rule 2012 Requirements for Monitoring, Reporting, and Recordkeeping for Oxides of Nitrogen (NOx) Emissions (Adopted 12/7/95)

5. *The following rules were submitted but will not be included until the District's Title V Operating Permits program has been approved:*

Rule 518 Variance Procedures for Title V Facilities (Adopted 8/11/95)
Rule 518.1 Permit Appeal Procedures for Title V Facilities (Adopted 8/11/95)
Rule 518.2 Federal Alternative Operating Conditions (Adopted 1/12/96)
Rule XXX Title V Permits (Adopted 8/11/95)

6. *The following rules were submitted but will not be included because they do not apply to OCS Sources:*

Rule 461 Gasoline Transfer and Dispensing (Adopted 9/8/95)
Rule 462 Organic Liquid Loading (Adopted 6/9/95)
Rule 1130 Graphic Arts (Adopted 9/8/95)
Rule 1166 Volatile Organic Compound Emissions from Decontamination of Soil (Adopted 7/14/95)

B. After review of the rules submitted by Ventura County APCD against the criteria set forth above and in 40 CFR part 55, EPA is proposing to make the following rules applicable to OCS sources for which Ventura County APCD is designated as the COA.

1. *The following rules were submitted as revisions to existing requirements:*

Rule 26.1 New Source Review—Definitions (Adopted 2/13/96)
Rule 26.2 New Source Review—Requirements (Adopted 2/13/96)
Rule 26.3 New Source Review—Exemptions (Adopted 2/13/96)
Rule 42 Permit Fees (Adopted 3/12/96)
Rule 44 Exemption Evaluation Fee (Adopted 10/10/95)
Rule 74.7 Fugitive Emissions of Reactive Organic Compounds (ROC) at Petroleum Refineries and Chemical Plants (Adopted 10/10/95)
Rule 74.23 Stationary Gas Turbines (Adopted 10/10/95)

2. *The following rule was submitted but will not be included because they are Administrative and/or Procedural:*

Rule 9 Arrest Authority (Adopted 3/12/96)
Rule 26.4 New Source Review—Emission Banking (Adopted 2/13/96)
Rule 26.5 New Source Review—Community Bank (Adopted 2/13/96)

3. *The following is a new rule to be included:*

Rule 76 Federally Enforceable Limits on Potential to Emit (Adopted 10/10/95)

Executive Order 12291 (Regulatory Impact Analysis)

The Office of Management and Budget has exempted this rule from the requirements of Section 3 of Executive Order 12291. This exemption continues in effect under Executive Order 12866 which superseded Executive Order 12291 on September 30, 1993.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 requires each federal agency to perform a Regulatory Flexibility Analysis for all rules that are likely to have a ''significant impact on a substantial number of small entities.'' Small entities include small businesses, organizations, and governmental jurisdictions.

As was stated in the final regulation, the OCS rule does not apply to any small entities, and the structure of the rule averts direct impacts and mitigates indirect impacts on small entities. This consistency update merely incorporates onshore requirements into the OCS rule to maintain consistency with onshore regulations as required by section 328 of the Act and does not alter the structure of the rule.

The EPA certifies that this notice of proposed rulemaking will not have a significant impact on a substantial number of small entities.

List of Subjects in 40 CFR Part 55

Environmental protection, Administrative practice and procedures, Air pollution control, Hydrocarbons,

Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Nitrogen oxides, Outer Continental Shelf, Ozone, Particulate matter, Permits, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: June 30, 1996.

Felicia Marcus,

Regional Administrator.

Title 40 of the Code of Federal Regulations, part 55, is proposed to be amended as follows:

PART 55—[AMENDED]

1. The authority citation for part 55 continues to read as follows:

Authority: Section 328 of the Clean Air Act (42 U.S.C. § 7401 *et seq.*) as amended by Public Law 101–549.

2. Section 55.14 is proposed to be amended by revising paragraphs (e)(3)(ii)(G), and (e)(3)(ii)(H) to read as follows:

§ 55.14 Requirements that apply to OCS sources located within 25 miles of states seaward boundaries, by state.

* * * * *

(e) * * *

(3) * * *

(ii) * * *

(G) *South Coast Air Quality Management District Requirements Applicable to OCS Sources* (Part I and Part II).

(H) *Ventura County Air Pollution Control District Requirements Applicable to OCS Sources.*

* * * * *

3. Appendix A to CFR Part 55 is proposed to be amended by revising paragraph (b)(7) and (8) under the heading ''California'' to read as follows:

Appendix A to 40 CFR Part 55—Listing of State and Local Requirements Incorporated by Reference Into Part 55, by State

* * * * *

California

* * * * *

(b) * * *

* * * * *

(7) The following requirements are contained in *South Coast Air Quality Management District Requirements Applicable to OCS Sources:*

Rule 102 Definition of Terms (Adopted 11/17/95)
Rule 103 Definition of Geographical Areas (Adopted 1/9/76)
Rule 104 Reporting of Source Test Data and Analyses (Adopted 1/9/76)
Rule 108 Alternative Emission Control Plans (Adopted 4/6/90)
Rule 109 Recordkeeping for Volatile Organic Compound Emissions (Adopted 3/6/92)
Rule 118 Emergencies (Adopted 12/8/95)
Rule 201 Permit to Construct (Adopted 1/5/90)
Rule 201.1 Permit Conditions in Federally Issued Permits to Construct (Adopted 1/5/90)
Rule 202 Temporary Permit to Operate (Adopted 5/7/76)
Rule 203 Permit to Operate (Adopted 1/5/90)
Rule 204 Permit Conditions (Adopted 3/6/92)
Rule 205 Expiration of Permits to Construct (Adopted 1/5/90)
Rule 206 Posting of Permit to Operate (Adopted 1/5/90)
Rule 207 Altering or Falsifying of Permit (Adopted 1/9/76)
Rule 208 Permit for Open Burning (Adopted 1/5/90)
Rule 209 Transfer and Voiding of Permits (Adopted 1/5/90)
Rule 210 Applications (Adopted 1/5/90)
Rule 212 Standards for Approving Permits (Adopted 12/7/95) except (e)
Rule 214 Denial of Permits (Adopted 1/5/90)
Rule 217 Provisions for Sampling and Testing Facilities (Adopted 1/5/90)
Rule 218 Stack Monitoring (Adopted 8/7/81)
Rule 219 Equipment Not Requiring a Written Permit Pursuant to Regulation II (Adopted 8/12/94)
Rule 220 Exemption—Net Increase in Emissions (Adopted 8/7/81)
Rule 221 Plans (Adopted 1/4/85)
Rule 301 Permit Fees (Adopted 10/13/95)
Rule 304 Equipment, Materials, and Ambient Air Analyses (Adopted 6/10/94)
Rule 304.1 Analyses Fees (Adopted 6/10/94)
Rule 305 Fees for Acid Deposition (Adopted 10/4/91)
Rule 306 Plan Fees (Adopted 6/10/94)
Rule 309 Fees for Regulation XVI (Adopted 6/10/94)
Rule 401 Visible Emissions (Adopted 4/7/89)
Rule 403 Fugitive Dust (Adopted 7/9/93)
Rule 404 Particulate Matter—Concentration (Adopted 2/7/86)
Rule 405 Solid Particulate Matter—Weight (Adopted 2/7/86)
Rule 407 Liquid and Gaseous Air Contaminants (Adopted 4/2/82)
Rule 408 Circumvention (Adopted 5/7/76)
Rule 409 Combustion Contaminants (Adopted 8/7/81)
Rule 429 Start-Up and Shutdown Provisions for Oxides of Nitrogen (Adopted 12/21/90)
Rule 430 Breakdown Provisions,(a)and e)only (Adopted 5/5/78)
Rule 431.1 Sulfur Content of Gaseous Fuels (Adopted 11/17/95)
Rule 431.2 Sulfur Content of Liquid Fuels (Adopted 5/4/90)
Rule 431.3 Sulfur Content of Fossil Fuels (Adopted 5/7/76)
Rule 441 Research Operations (Adopted 5/7/76)
Rule 442 Usage of Solvents (Adopted 3/5/82)
Rule 444 Open Fires (Adopted 10/2/87)
Rule 463 Organic Liquid Storage (Adopted 3/11/94)
Rule 465 Vacuum Producing Devices or Systems (Adopted 11/1/91)
Rule 468 Sulfur Recovery Units (Adopted 10/8/76)
Rule 473 Disposal of Solid and Liquid Wastes (Adopted 5/7/76)
Rule 474 Fuel Burning Equipment-Oxides of Nitrogen (Adopted 12/4/81)
Rule 475 Electric Power Generating Equipment (Adopted 8/7/78)
Rule 476 Steam Generating Equipment (Adopted 10/8/76)
Rule 480 Natural Gas Fired Control Devices (Adopted 10/7/77) Addendum to Regulation IV (Effective 1977)
Rule 701 Air Pollution Emergency Contingency Actions (Adopted 9/8/95)
Rule 702 Definitions (Adopted 7/11/80)
Rule 704 Episode Declaration (Adopted 7/9/82)
Rule 707 Radio—Communication System (Adopted 7/11/80)
Rule 708 Plans (Adopted 7/9/82)
Rule 708.1 Stationary Sources Required to File Plans (Adopted 4/4/80)
Rule 708.2 Content of Stationary Source Curtailment Plans (Adopted 4/4/80)
Rule 708.4 Procedural Requirements for Plans (Adopted 7/11/80)
Rule 709 First Stage Episode Actions (Adopted 7/11/80)
Rule 710 Second Stage Episode Actions (Adopted 7/11/80)
Rule 711 Third Stage Episode Actions (Adopted 7/11/80)
Rule 712 Sulfate Episode Actions (Adopted 7/11/80)
Rule 715 Burning of Fossil Fuel on Episode Days (Adopted 8/24/77) Regulation IX—New Source Performance Standards (Adopted 4/8/94)
Rule 1106 Marine Coatings Operations (Adopted 1/13/95)
Rule 1107 Coating of Metal Parts and Products (Adopted 5/12/95)
Rule 1109 Emissions of Oxides of Nitrogen for Boilers and Process Heaters in Petroleum Refineries (Adopted 8/5/88)
Rule 1110 Emissions from Stationary Internal Combustion Engines (Demonstration) (Adopted 11/6/81)
Rule 1110.1 Emissions from Stationary Internal Combustion Engines (Adopted 10/4/85)
Rule 1110.2 Emissions from Gaseous and Liquid-Fueled Internal Combustion Engines (Adopted 12/9/94)
Rule 1113 Architectural Coatings (Adopted 9/6/91)
Rule 1116.1 Lightering Vessel Operations-Sulfur Content of Bunker Fuel (Adopted 10/20/78)
Rule 1121 Control of Nitrogen Oxides from Residential-Type Natural Gas-Fired Water Heaters (Adopted 3/10/95)
Rule 1122 Solvent Cleaners (Degreasers) (Adopted 4/5/91)
Rule 1123 Refinery Process Turnarounds (Adopted 12/7/90)
Rule 1129 Aerosol Coatings (Adopted 11/2/90)

Rule 1134 Emissions of Oxides of Nitrogen from Stationary Gas Turbines (Adopted 12/7/95)
Rule 1136 Wood Products Coatings (Adopted 9/8/95)
Rule 1140 Abrasive Blasting (Adopted 8/2/85)
Rule 1142 Marine Tank Vessel Operations (Adopted 7/19/91)
Rule 1146 Emissions of Oxides of Nitrogen from Industrial, Institutional, and Commercial Boilers, Steam Generators, and Process Heaters (Adopted 5/13/94)
Rule 1146.1 Emission of Oxides of Nitrogen from Small Industrial, Institutional, and Commercial Boilers, Steam Generators, and Process Heaters (Adopted 5/13/94)
Rule 1148 Thermally Enhanced Oil Recovery Wells (Adopted 11/5/82)
Rule 1149 Storage Tank Degassing (Adopted 7/14/95)
Rule 1168 Control of Volatile Organic Compound Emissions from Adhesive Application (Adopted 12/10/93)
Rule 1171 Solvent Cleaning Operations (Adopted 5/12/95)
Rule 1173 Fugitive Emissions of Volatile Organic Compounds (Adopted 5/13/94)
Rule 1176 Sumps and Wastewater Separators (Adopted 5/13/94)
Rule 1301 General (Adopted 12/7/95)
Rule 1302 Definitions (Adopted 12/7/95)
Rule 1303 Requirements (Adopted 12/7/95)
Rule 1304 Exemptions (Adopted 12/7/95)
Rule 1306 Emission Calculations (Adopted 12/7/95)
Rule 1313 Permit to Operate (Adopted 12/7/95)
Rule 1403 Asbestos Emissions from Demolition/Renovation Activities (Adopted 4/8/94)
Rule 1610 Old-Vehicle Scrapping (Adopted 10/13/95)
Rule 1612 Credits for Clean On-Road Vehicles (Adopted 9/8/95)
Rule 1620 Credits for Clean Off-Road Mobile Equipment (Adopted 9/8/95)
Rule 1701 General (Adopted 1/6/89)
Rule 1702 Definitions (Adopted 1/6/89)
Rule 1703 PSD Analysis (Adopted 10/7/88)
Rule 1704 Exemptions (Adopted 1/6/89)
Rule 1706 Emission Calculations (Adopted 1/6/89)
Rule 1713 Source Obligation (Adopted 10/7/88)
Regulation XVII Appendix (effective 1977)
Rule 1901 General Conformity (Adopted 9/9/94)
Rule 2000 General (Adopted 12/7/95)
Rule 2001 Applicability (Adopted 12/7/95)
Rule 2002 Allocations for oxides of nitrogen (NO_X) and oxides of sulfur (SO_X) Emissions (Adopted 12/7/95)
Rule 2004 Requirements (Adopted 12/7/95)
Rule 2005 New Source Review for RECLAIM (Adopted 12/7/95) except (i)
Rule 2006 Permits (Adopted 12/7/95)
Rule 2007 Trading Requirements (Adopted 12/7/95)
Rule 2008 Mobiles Source Credits (Adopted 10/15/93)
Rule 2010 Administrative Remedies and Sanctions (Adopted 10/15/93)
Rule 2011 Requirements for Monitoring, Reporting, and Recordkeeping for Oxides of Sulfur (SOx) Emissions (Adopted 10/15/93)
Appendix A Volume IV—(Protocol for oxides of sulfur) (Adopted 9/8/95)
Rule 2012 Requirements for Monitoring, Reporting, and Recordkeeping for Oxides of Nitrogen (NOx) Emissions (Adopted 10/13/93)
Appendix A Volume V—(Protocol for oxides of nitrogen) (Adopted 9/8/95)
Rule 2015 Backstop Provisions (Adopted 12/7/95) except (b)(1)(G) and (b)(3)(B)
Rule 2100 Registration of Portable Equipment (Adopted 12/7/95)
XXXI Acid Rain Permit Program (Adopted 2/10/95)

(8) The following requirements are contained in *Ventura County Air Pollution Control District Requirements Applicable to OCS Sources:*

Rule 2 Definitions (Adopted 12/15/92)
Rule 5 Effective Date (Adopted 5/23/72)
Rule 6 Severability (Adopted 11/21/78)
Rule 7 Zone Boundaries (Adopted 6/14/77)
Rule 10 Permits Required (Adopted 6/13/95)
Rule 11 Definition for Regulation II (Adopted 6/13/95)
Rule 12 Application for Permits (Adopted 6/13/95)
Rule 13 Action on Applications for an Authority to Construct (Adopted 6/13/95)
Rule 14 Action on Applications for a Permit to Operate (Adopted 6/13/95)
Rule 15.1 Sampling and Testing Facilities (Adopted 10/12/93)
Rule 16 BACT Certification (Adopted 6/13/95)
Rule 19 Posting of Permits (Adopted 5/23/72)
Rule 20 Transfer of Permit (Adopted 5/23/72)
Rule 23 Exemptions from Permits (Adopted 12/13/94)
Rule 24 Source Recordkeeping, Reporting, and Emission Statements (Adopted 9/15/92)
Rule 26 New Source Review (Adopted 10/22/91)
Rule 26.1 New Source Review—Definitions (Adopted 2/13/96)
Rule 26.2 New Source Review—Requirements (Adopted 2/13/96)
Rule 26.3 New Source Review—Exemptions (Adopted 2/13/96)
Rule 26.6 New Source Review—Calculations (Adopted 10/22/91)
Rule 26.8 New Source Review—Permit To Operate (Adopted 10/22/91)
Rule 26.10 New Source Review—PSD (Adopted 10/22/91)
Rule 28 Revocation of Permits (Adopted 7/18/72)
Rule 29 Conditions on Permits (Adopted 10/22/91)
Rule 30 Permit Renewal (Adopted 5/30/89)
Rule 32 Breakdown Conditions: Emergency Variances, A., B.1., and D. only. (Adopted 2/20/79)
Rule 33 Part 70 Permits—General (Adopted 10/12/93)
Rule 33.1 Part 70 Permits—Definitions (Adopted 10/12/93)
Rule 33.2 Part 70 Permits—Application Contents (Adopted 10/12/93)
Rule 33.3 Part 70 Permits—Permit Content (Adopted 10/12/93)
Rule 33.4 Part 70 Permits—Operational Flexibility (Adopted 10/12/93)
Rule 33.5 Part 70 Permits—Timeframes for Applications, Review and Issuance (Adopted 10/12/93)
Rule 33.6 Part 70 Permits—Permit Term and Permit Reissuance (Adopted 10/12/93)
Rule 33.7 Part 70 Permits—Notification (Adopted 10/12/93)
Rule 33.8 Part 70 Permits—Reopening of Permits (Adopted 10/12/93)
Rule 33.9 Part 70 Permits—Compliance Provisions (Adopted 10/12/93)
Rule 33.10 Part 70 Permits—General Part 70 Permits (Adopted 10/12/93)
Rule 34 Acid Deposition Control (Adopted 3/14/95)
Appendix II–B Best Available Control Technology (BACT) Tables (Adopted 12/86)
Rule 42 Permit Fees (Adopted 3/12/96)
Rule 44 Exemption Evaluation Fee (Adopted 10/10/95)
Rule 45 Plan Fees (Adopted 6/19/90)
Rule 45.2 Asbestos Removal Fees (Adopted 8/4/92)
Rule 50 Opacity (Adopted 2/20/79)
Rule 52 Particulate Matter-Concentration (Adopted 5/23/72)
Rule 53 Particulate Matter-Process Weight (Adopted 7/18/72)
Rule 54 Sulfur Compounds (Adopted 6/14/94)
Rule 56 Open Fires (Adopted 3/29/94)
Rule 57 Combustion Contaminants-Specific (Adopted 6/14/77)
Rule 60 New Non-Mobile Equipment-Sulfur Dioxide, Nitrogen Oxides, and Particulate Matter (Adopted 7/8/72)
Rule 62.7 Asbestos—Demolition and Renovation (Adopted 6/16/92)
Rule 63 Separation and Combination of Emissions (Adopted 11/21/78)
Rule 64 Sulfur Content of Fuels (Adopted 6/14/94)
Rule 66 Organic Solvents (Adopted 11/24/87)
Rule 67 Vacuum Producing Devices (Adopted 7/5/83)
Rule 68 Carbon Monoxide (Adopted 6/14/77)
Rule 71 Crude Oil and Reactive Organic Compound Liquids (Adopted 12/13/94)
Rule 71.1 Crude Oil Production and Separation (Adopted 6/16/92)
Rule 71.2 Storage of Reactive Organic Compound Liquids (Adopted 9/26/89)
Rule 71.3 Transfer of Reactive Organic Compound Liquids (Adopted 6/16/92)
Rule 71.4 Petroleum Sumps, Pits, Ponds, and Well Cellars (Adopted 6/8/93)
Rule 71.5 Glycol Dehydrators (Adopted 12/13/94)
Rule 72 New Source Performance Standards (NSPS) (Adopted 6/28/94)
Rule 74 Specific Source Standards (Adopted 7/6/76)
Rule 74.1 Abrasive Blasting (Adopted 11/12/91)
Rule 74.2 Architectural Coatings (Adopted 08/11/92)

Rule 74.6 Surface Cleaning and Degreasing (Adopted 5/8/90)
Rule 74.6.1 Cold Cleaning Operations (Adopted 9/12/89)
Rule 74.6.2 Batch Loaded Vapor Degreasing Operations (Adopted 9/12/89)
Rule 74.7 Fugitive Emissions of Reactive Organic Compounds (ROC) at Petroleum Refineries and Chemical Plants (Adopted 10/10/95)
Rule 74.8 Refinery Vacuum Producing Systems, Waste-water Separators and Process Turnarounds (Adopted 7/5/83)
Rule 74.9 Stationary Internal Combustion Engines (Adopted 12/21/93)
Rule 74.10 Components at Crude Oil Production Facilities and Natural Gas Production and Processing Facilities (Adopted 6/16/92)
Rule 74.11 Natural Gas-Fired Residential Water Heaters-Control of NO_X (Adopted 4/9/85)
Rule 74.12 Surface Coating of Metal Parts and Products (Adopted 12/13/94)
Rule 74.15 Boilers, Steam Generators and Process Heaters (5MM BTUs and greater) (Adopted 11/8/94)
Rule 74.15.1 Boilers, Steam Generators and Process Heaters (1–5MM BTUs)(Adopted 6/13/95)
Rule 74.16 Oil Field Drilling Operations (Adopted 1/8/91)
Rule 74.20 Adhesives and Sealants (Adopted 6/8/93)
Rule 74.23 Stationary Gas Turbines (Adopted 10/10/95)
Rule 74.24 Marine Coating Operations (Adopted 3/8/94)
Rule 74.26 Crude Oil Storage Tank Degassing Operations (Adopted 11/8/94)
Rule 74.27 Gasoline and ROC Liquid Storage Tank Degassing Operations (Adopted 11/8/94)
Rule 74.28 Asphalt Roofing Operations (Adopted 5/10/94)
Rule 74.30 Wood Products Coatings (Adopted 5/17/94)
Rule 75 Circumvention (Adopted 11/27/78)
Rule 76 Federally Enforceable Limits on Potential to Emit (Adopted 10/10/95)
Appendix IV–A Soap Bubble Tests (Adopted 12/86)
Rule 100 Analytical Methods (Adopted 7/18/72)
Rule 101 Sampling and Testing Facilities (Adopted 5/23/72)
Rule 102 Source Tests (Adopted 11/21/78)
Rule 103 Stack Monitoring (Adopted 6/4/91)
Rule 154 Stage 1 Episode Actions (Adopted 9/17/91)
Rule 155 Stage 2 Episode Actions (Adopted 9/17/91)
Rule 156 Stage 3 Episode Actions (Adopted 9/17/91)
Rule 158 Source Abatement Plans (Adopted 9/17/91)
Rule 159 Traffic Abatement Procedures (Adopted 9/17/91)
Rule 220 General Conformity (Adopted 5/9/95)

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DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

49 CFR Part 397

[FHWA Docket No. MC–96–10]

Recommendations on Uniform Forms and Procedures for the Transportation of Hazardous Materials

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of report availability; request for comments.

SUMMARY: The FHWA is requesting public comment on the final report and recommendations of the Alliance for Uniform HazMat Transportation Procedures (the Alliance) concerning the implementation of 49 U.S.C. 5119—formerly referred to as section 22 of the Hazardous Materials Transportation Uniform Safety Act of 1990 (HMTUSA). Section 5119 requires the Secretary of Transportation (the Secretary) to establish a working group of State and local government officials to establish uniform forms and procedures for the registration of persons that transport hazardous materials by motor vehicle, and to decide whether to limit the filing of State registration and permit forms and the collection of filing fees. The Alliance is the working group created to fulfill the requirements of the HMTUSA, and accordingly, has published its final report with recommendations which is now available to the public.

DATES: Written comments must be received on or before November 6, 1996.

ADDRESSES: Submit written, signed comments to FHWA Docket No. MC–96-10, room 4232, HCC–10, Office of the Chief Counsel, Federal Highway Administration, 400 Seventh Street, SW., Washington, D. C. 20590. All comments received will be available for examination at the above address from 8:30 a.m. to 3:30 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard.

FOR FURTHER INFORMATION CONTACT: Mr. Larry W. Minor, Office of Motor Carrier Research and Standards, (202) 366–4009; Mr. James D. McCauley, Office of Motor Carrier Safety and Technology, (202) 366–9579; or Mr. Raymond W. Cuprill, Office of Chief Counsel, (202) 366–0834, Federal Highway Administration, 400 Seventh Street, SW., Washington, D. C. 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Section 5119 of Title 49, United States Code, requires that the Secretary establish a working group of State and local government officials to develop recommendations on uniform forms and procedures that the States can use to register and permit persons that transport, or cause the transportation of, hazardous materials by motor vehicle. The working group is also required to make recommendations as to whether the filing of registration and permit forms, and the collection of related fees, should be limited to the State in which a person resides or has its principal place of business. In developing its recommendations, the group is required to consult with persons who are subject to these registration and permit requirements. The recommendations of the working group are to be included in a final report to the Secretary of Transportation.[1] Finally, section 5119 requires the issuance of regulations implementing those recommendations with which the Secretary agrees.

Section 5119 was originally enacted as section 22 of the Hazardous Materials Transportation Uniform Safety Act of 1990 (Pub. L. 101–615, 104 Stat. 3244; November 16, 1990). The HMTUSA amended the Hazardous Materials Transportation Act of 1974 (HMTA), Public Law 93–633, 88 Stat. 2156, which granted regulatory and enforcement authority to the Secretary to provide adequate protection against the risks to life and property inherent in the transportation of hazardous materials in commerce. The HMTA was designed to replace a patchwork of State and Federal laws and regulations concerning hazardous materials transportation with a scheme of uniform, national regulations. The HMTA and HMTUSA were repealed by Public Law 103–272 (108 Stat. 745, 1379; July 5, 1994) with the statutory provisions applicable to the transportation of hazardous materials recodified at 49 U.S.C. 5101 *et seq.*

Implementation of Section 5119

A. Creation of the Alliance for Uniform HazMat Transportation Procedures

In 1991, the National Governors' Association (NGA) and the National Conference of State Legislatures (NCSL) were awarded a contract to coordinate the staffing and operations of the

[1] The report is to be also submitted to the Committee on Commerce, Science, and Transportation of the Senate, and the Committee on Public Works and Transportation of the House of Representatives.

working group. The NGA and NCSL presented recommendations to the Secretary for the establishment of a panel to carry out the tasks of the working group. The panel was approved by the Secretary and held its first meeting in January 1992, at which time it selected the title ''the Alliance for Uniform HazMat Transportation Procedures'' or ''the Alliance.''

The Alliance authorized the formation of four subgroups to address specific areas of State hazardous materials transportation regulation. Industry representatives were invited to participate in the subgroups. The subgroups were:

1. Shipper and Carrier Registration Subgroup;
2. Shipper and Carrier Permitting and Licensing Subgroup;
3. Operational Issues Subgroup; and,
4. Audit and Enforcement Subgroup.

Each subgroup was asked to examine current State practices, identify the extent to which State practices are uniform, identify barriers to uniformity, and make recommendations for criteria on which a uniform State program would be based.

One of the key decisions to come out of the registration subgroup concerned shippers. After reviewing results from surveys of the States, the subgroup decided not to recommend a shipper registration program separate from the Federal program operated by the Research and Special Programs Administration (RSPA).[2] (The RSPA's hazardous materials registration and fee assessment program are discussed later in this document.) Therefore, the following discussion of the Alliance's program only pertains to motor carriers.

B. Pilot Study

In May of 1992, the Alliance proceeded with the design and implementation of a two-year pilot project. The project was based upon the following assumptions/recommendations:

1. Base-state system for registration and collection of fees;
2. Reciprocity between states that require permits;
3. Additional information for hazardous waste transporters;
4. Individual state enforcement authority;
5. Participation by localities; and,
6. Establishment of a governing board to manage the pilot project.

Based upon the Alliance's recommendations, the FHWA funded a two-year demonstration program for four States. During the first year, each State would develop the internal administrative procedures and organization to conduct a test of the Alliance's recommended program. During the second year, the States would implement the program for motor carriers involved in the transportation of hazardous materials.

In November of 1992, the Alliance contacted State hazardous materials transportation program administrators to solicit participation in the pilot study. The States of Minnesota, Nevada, Ohio, and West Virginia were chosen based upon the following criteria established by the Alliance:

1. The Governor and State legislature were committed to taking the necessary legislative and administrative actions to conduct the State's hazardous materials transportation programs under the principles and operating procedures of the Alliance's recommendations;
2. The regulated community within the State was committed to supporting participation in the program;
3. The State had experience in the registration and permitting of hazardous materials, and/or in the transportation of radioactive materials;
4. The group of States chosen reflected ''geographic diversity;''
5. At least one pilot State had a ''major locality'' with a hazardous materials transportation registration or permitting program.

On July 1, 1993, the pilot States began registering and permitting motor carriers in accordance with the Alliance's recommendations. Each participating State was given the opportunity to select one of the following three options for implementing the Alliance's Uniform Program:

1. The State could apply the requirements of the Uniform Program to all motor carriers (interstate and intrastate); or
2. The State could apply the requirements only to domiciled, interstate motor carriers that operate in two or more of the pilot States; or,
3. The State could select an even smaller sample of interstate motor carriers.

Minnesota, Ohio, and West Virginia used option one while Nevada selected option two for the first round of registration and permitting with the intent of expanding the program to all motor carriers during the second program year.

C. The Alliance's Findings and Conclusions

On March 15, 1996, the Alliance submitted its final report and recommendations to the FHWA. The Alliance concluded that the pilot study met the uniformity mandate of 49 U.S.C. 5119. The report states that all of the pilot States support the program and believe that other States should join the program to increase the benefits provided by this uniform program and to spread the administrative load presented by multi-state carriers. The report claims that industry participants also support making the program uniform in all States, although the industry believes that a shorter application form and a simplified formula for calculating fees should be used.

The Alliance recommends that the Secretary:

1. Explore options for the consolidation of Federal and State registration programs;
2. Consider waiving the Federal requirement for motor carriers that have obtained a permit under the Uniform Program; and
3. Promote a one-stop repository for up-to-date information on hazardous materials routing designations.

In addition, the Alliance's Governing Board, which was responsible for managing the pilot program, recommends that the Congress amend section 5119 to require that any jurisdiction that elects to register and/or permit motor carriers to transport hazardous materials, must do so in conformity with the Alliance's Uniform Program. The Board recommends that the Secretary retain the authority to preempt any State program or program provision that the Secretary determines is inconsistent with the uniformity mandate. Additionally, the Board recommends that the Congress establish a deadline (not less than three years) for compliance with the mandate and provide financial support to the Alliance to facilitate State entry into the Uniform Program.

Other Federal and State Initiatives

There are several major activities underway which may have an impact or may be related to the State hazardous materials transportation registration and permitting processes. These activities include: (1) The FHWA's motor carrier safety permits and inspection rulemaking; (2) the Research and Special Program Administration's (RSPA) Hazardous Materials Registration and Fee Assessment Program; (3) the Commercial Vehicle Information System (CVIS) feasibility study; and (4) the elimination of the Interstate Commerce Commission (ICC) and the transfer of the ICC's registration (operating authority) and insurance programs to the FHWA. All of these

[2] *Alliance Phase One Subgroup Reports*, National Governors' Association-National Conference of State Legislatures, June 1992. A copy of this document is included in the docket file.

initiatives, as well as the FHWA's motor carrier registration requirement—the motor carrier identification report (Form MCS–150) required by 49 CFR 385.21 and used by the FHWA to assign USDOT numbers—and the registration and insurance filings of for-hire motor carriers required by many States (Single State Registration System), are very similar or related. However, these programs are commonly administered as separate functions by several agencies within a State.

These activities may have a significant bearing on the public comments offered in response to this notice and on the ultimate direction of any resulting rulemaking actions affecting Federal and State registration and permitting of transporters and shippers of hazardous materials. The FHWA encourages comments on the relationship between the recommendations of the Alliance and the activities discussed in this notice.

FHWA Rulemaking on Motor Carrier Safety Permits and the Inspection of Vehicles Transporting Highway-Route-Controlled Quantities of Radioactive Materials [49 U.S.C. 5109(a) and 5105(e)]

Section 5109(a), Motor Carrier Safety Permits (originally enacted as one of the provisions of section 8 of the HMTUSA), provides that a motor carrier shall only transport, or cause the transportation of, hazardous materials in commerce if the carrier holds a safety permit issued by the Secretary and keeps a copy of the permit, or other proof of its existence, in the vehicle. The Secretary is required to prescribe by regulation the hazardous materials and amounts to which the permit requirement applies. However, the list of hazardous materials must include, at a minimum and in amounts established by the Secretary, the following:

(1) Division 1.1, 1.2, and 1.3 (class A or B explosives);

(2) liquefied natural gas;

(3) hazardous material the Secretary designates as extremely toxic by inhalation; and

(4) a highway-route-controlled quantity of radioactive material, as defined by the Secretary.

Section 5105(e), Inspections of Motor Vehicles Transporting Certain Material (originally enacted as section 15 of the HMTUSA), directs the Secretary to issue regulations requiring that each motor vehicle transporting a highway-route-controlled quantity of Class 7 (radioactive) material in commerce be inspected and certified as complying with the Federal hazardous materials and motor carrier safety laws and regulations. The Secretary may require the inspections to be conducted by Federal inspectors or in accordance with appropriate State procedures. The Secretary may allow self-certification by motor carriers using employees that meet minimum qualifications set by the Secretary.

On June 17, 1993, the FHWA published a notice of proposed rulemaking (NPRM) to implement the requirements of 49 U.S.C. 5109 and 5105 (58 FR 33418). The FHWA proposed to amend part 397 of the Federal Motor Carrier Safety Regulations (FMCSRs) by adding a new subpart B, Motor Carrier Safety Permits. The notice proposed to initially limit the safety permit program to the transportation of the four classes of hazardous materials set forth in the statute, with phase-in periods for Division 1.1, 1.2 and 1.3 materials (Class A and B explosives)[3] and limiting the materials considered extremely toxic by inhalation to those that meet the criteria of Division 2.3, Hazard Zone A, or Division 6.1, Packing Group I, Hazard Zone A (see 49 CFR 173.115 and 173.132) and are transported in quantities of more than 1 liter (1.06 quarts). The proposed permit procedures made extensive use of existing FHWA programs, forms and procedures, and as a result, the agency proposed not to assess permit fees. To obtain a permit, a motor carrier would be required to submit a revised MCS–150 (Motor Carrier Identification Report) to the Regional Director, Office of Motor Carriers, for the region in which the motor carrier has its principal place of business. Determinations on safety permit applications would be based upon a safety fitness finding made pursuant to 49 CFR part 385. A ''satisfactory'' safety rating would be a prerequisite to the granting of a safety permit. A less than ''satisfactory'' safety rating would result in a denial of the permit application. The FHWA would have the discretion to issue a temporary safety permit (120 days) to an unrated motor carrier pending a safety fitness determination. Safety permits would be valid for three years and would be renewable. Reviews of the FHWA's determinations on permit issuance would be handled pursuant to the existing procedures applicable to safety rating reviews (49 CFR 385.15 and 385.17). The current safety rating notification letter would be modified to serve as the safety permit. The letter would bear a safety permit number, which would be the motor carrier's identification or census number assigned by the FHWA when the motor carrier submits the MCS–150 required by § 385.21. Motor carriers would be required to display this permit number on the shipping papers and on the commercial motor vehicles used.

With regard to the inspection requirements of 49 U.S.C. 5105, the FHWA proposed that motor carriers transporting highway-route-controlled quantities of Class 7 (radioactive) materials be required to inspect each commercial motor vehicle used before each trip and that a written certification by a qualified inspector be maintained. It was proposed that these vehicles be inspected through the use of the general inspection requirements contained in 49 CFR part 396, ''Inspection, Repair, and Maintenance,'' and the more detailed inspection standards found in appendix G to 49 CFR subchapter B, ''Minimum Periodic Inspection Standards.'' The inspector qualification requirements for the periodic inspection (specified in 49 CFR 396.19) would be used to ensure that inspectors are qualified to perform the vehicle inspections.

The FHWA carefully reviewed the various registration and permitting requirements of the Federal law and decided not to proceed with further rulemaking action to implement the requirements of 49 U.S.C. 5109 and 5105 until it had considered the final report and recommendations of the Alliance for implementing section 5119. This was considered the most effective way to satisfy all of these related statutory requirements, as the Alliance's recommendations would have a significant bearing on the implementation of the Federal safety permit and inspection requirements.

Federal Hazardous Materials Registration and Fee Assessment Program and the Hazardous Materials Emergency Preparedness Grant Program

Section 5108(a)(1) (originally enacted as one of the provisions of section 8 of the HMTUSA) requires that each person transporting or causing to be transported in commerce the following hazardous materials must file a ''registration statement'' with the Secretary:

(1) Highway-route-controlled quantities of Class 7 (radioactive) materials;

(2) more than 25 kilograms of Division 1.1, 1.2 and 1.3 (explosives) materials;

[3] The proposed phase-in period was to be implemented as follows:

Effective date and covered quantities of class A and/or B explosives:

Nov. 16, 1993—454 kilograms (1,000 pounds) or more.

Nov. 16, 1994—227 kilograms (500 pounds) or more.

Nov. 16, 1995—25 kilograms (55 pounds) or more.

(3) more than 1 liter in each package of a hazardous material which has been designated by the Secretary as extremely toxic by inhalation;

(4) hazardous material in a bulk package, container, or tank as defined by the Secretary if the package, container, or tank has a capacity of 13,249 or more liters (3,500 or more gallons) or has a volume greater than 13.25 cubic meters (468 cubic feet);

(5) a shipment of at least 2,268 kg (5,000 pounds) (except in a bulk packaging) of a class of hazardous material requiring a placard.

In addition, section 5108(a)(2) provides the Secretary with discretionary authority to require any of the following persons to file a registration statement:

(1) A person transporting or causing to be transported hazardous materials in commerce and not covered by section 5108(a)(1);

(2) a person manufacturing, fabricating, marking, maintaining, reconditioning, repairing, or testing a package or container the person represents, marks or certifies, or sells for use in transporting in commerce hazardous material the Secretary designates.

Paragraph (g) of section 5108 authorizes the Secretary to establish, impose, and collect a fee for the processing of the registration statement as well as an annual fee.

Implementation of these requirements was delegated by the Secretary to the RSPA. Federal registration of hazardous materials offerors and transporters began in 1992 (57 FR 30620, July 9, 1992). Federal registration is required of persons engaged in certain activities that involve the offering or transporting of hazardous materials in interstate, intrastate, or foreign commerce by highway, rail, air, or water. Less than half of the current registrants have identified themselves as highway carriers. The Federal registration program has no preemptive effect upon State and local hazardous materials registration programs.

The annual fee is used to fund grants to State and Indian tribal governments for hazardous materials planning and training purposes. The funds are allocated through the RSPA's Federal Hazardous Materials Emergency Preparedness (HMEP) Grant Program with the first grants awarded to qualifying State and Indian tribal governments in 1993.

In cooperation with the Alliance's pilot program, the concept of ''one-stop shopping'' for Federal and State registration of motor carriers was tested by the Public Utilities Commission of Ohio (PUCO) and the RSPA. Motor carriers required to register with the State of Ohio were provided with the option of also submitting the Federal registration statement and fee to the PUCO for transmittal to the RSPA. For the 1994–95 registration year (from July 1, 1994 to June 30, 1995), approximately 200 persons registered in the Federal program through the PUCO. During the 1995–96 registration year, the number of persons choosing this option decreased sharply to 76 persons. Only 16 of the participants in the 1994–95 registration year elected to use this process for the 1995–96 registration year.

The Alliance's report, discussed above, recommends that the Secretary explore the consolidation of Federal and State registration programs. The FHWA notes, however, that there are substantial differences between the existing Federal registration program and the program recommended by the Alliance. Commenters should familiarize themselves thoroughly with the purpose and scope of coverage of each program in preparation for providing comments regarding this recommendation by the Alliance.

The Commercial Vehicle Information System (CVIS)

The CVIS project is a feasibility study mandated by 49 U.S.C. 31106, which was originally enacted by section 4003 of the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA) (Pub. L. 102–240, 105 Stat. 1914, 2144; December 8, 1991). Specifically, the CVIS ties commercial motor vehicle registration privileges to a motor carrier's safety performance. For the first time, chronically unsafe motor carriers risk losing their vehicle registration privileges if they prove unable or unwilling to improve their operational safety levels after a designated period. The project is a cooperative effort involving the FHWA and five pilot States: Iowa (the lead State), Oregon, Colorado, Minnesota, and Indiana.

Motor carriers are identified for inclusion in the CVIS improvement process (MCSIP—Motor Carrier Safety Improvement Process) through the application of a carrier identification and prioritization algorithm referred to as the Safestat Identification Algorithm (Safestat). Safestat identifies ''At Risk'' motor carriers by producing a safety score for every interstate motor carrier. Motor carriers are ranked on a worst-first basis. Motor carriers with the lowest scores are considered to be ''At Risk'' and are scheduled for a compliance review (on-site visit), while motor carriers with less severe safety scores receive ''warning letters.'' Once a motor carrier has been identified for entry into the MCSIP, its safety performance is monitored using a second algorithm called the Safestat Monitoring Algorithm. The MCSIP process has been designed to provide numerous opportunities for motor carriers to improve their safety performance. Failure to improve safety performance, however, will result in progressively more severe penalties leading eventually to suspension or revocation of vehicle registration privileges.

The CVIS could be used to identify hazardous materials (HM) carriers that are ''At Risk'' by modifying the Safestat Identification Algorithm to include additional information about HM motor carriers. In fact, it has been suggested that a separate safety evaluation area relating to HM be included in the Safestat Identification Algorithm. Under this proposal, HM carriers that have been identified for entry into the MCSIP process and continue to score poorly may have their HM permits denied or suspended.

Interstate Commerce Commission's (ICC) Carrier Registration and Insurance Requirements

On December 29, 1995, the President signed the ICC Termination Act of 1995 (the Act) (Pub.L. 104–88, 109 Stat. 803), which eliminates the ICC and transfers certain motor carrier regulatory functions from the ICC to the FHWA. The principal functions being transferred are the licensing/registration activities, insurance tracking, Mexican motor carrier oversight, and responsibilities for brokers, freight forwarders, and household goods carriers. All past operating authority licenses and financial responsibility filings will remain valid, and all pending applications and financial responsibility filings will be processed by the FHWA. Future applications and insurance filings will continue to be accepted by the FHWA. The Act provides that registration generally remains in effect for up to five years unless it is suspended, amended, or revoked. Reasons for suspension or revocation may include unsafe operations, lack of the required financial responsibility coverage, or failure to comply with regulatory requirements.

The ICC and the FHWA motor carrier programs have the common goal of ensuring that motor carriers are properly identified, have adequate levels of financial responsibility, and operate in a safe manner. Under the present programs, for-hire motor carriers are registered and must show proof of

financial responsibility and familiarity with the FHWA's safety regulations. The financial responsibility coverage of for-hire motor carriers is continuously monitored. Policy pre-expiration notices obtained from the insurance companies as well as internal audits are used to determine compliance. Prior to an insurance policy lapsing, the carrier is contacted. Enforcement action, including litigation, can be used to stop the carrier from operating without financial responsibility. A carrier's operating authority can be revoked if financial responsibility is not obtained. A similar procedure applies to motor carriers that have been authorized to self-insure.

The Single State Registration System (SSRS) program was created to succeed the ''bingo card'' program administered by the ICC. The SSRS program is a base-State system whereby a motor carrier registers its interstate operating authority with and provides proof of financial responsibility coverage to one State (a base-State) instead of multiple States. The base State then distributes the collected fees to other participating States in which the motor carrier's vehicles operate. State participation in the System was limited to those States participating in the bingo card program prior to January 1991. Fee amounts were limited to those imposed prior to November 1991, not to exceed $10 per vehicle.

Under the Act, the SSRS will continue to operate. However, the Department is required to consolidate the current USDOT identification number system, the SSRS, the ICC registration system (including financial responsibility registration) into a single, on-line Federal system. The new system will contain information on, and identification of, all foreign and domestic motor carriers, brokers, and freight forwarders (as well as others required to register with the Department of Transportation) as well as information on safety fitness and compliance with the required levels of financial responsibility coverage. The Secretary may establish fees to fully operate the system, including any personnel to support the overall registration and financial responsibility filing system.

Request for Comments

The FHWA requests comments on the Alliance's final report and recommendations, as outlined in this notice. As discussed above, several major activities related to the hazardous materials transportation registration and permitting processes are also underway. The FHWA encourages commenters to consider these activities and their relationship to the final report and recommendations of the Alliance. Based upon the comments received, the FHWA may hold public meetings to further discuss these issues.

Copies of the report (''Final Report: Uniform Program Pilot Project,'' March 15, 1996) may be ordered at no charge from the National Governors' Association. Requests should be addressed to: National Governors' Association, c/o Mr. Kyle Winston, Hall of the States, 444 North Capitol Street, Suite 267, NW., Washington, D.C. 20001–1512. Request for copies may also be made by calling the NGA at (202) 624–5300 or via fax (202) 624–5395.

All comments received before the close of business on the comment closing date indicated above will be considered and will be available for examination in the docket at the above address. Comments received after the comment closing date will be filed in the docket and will be considered to the extent practical. In addition to late comments, the FHWA will also continue to file relevant information in the docket as it becomes available after the closing date. Interested persons should continue to examine the docket for new material.

List of Subjects in 49 CFR Part 397

Hazardous materials transportation, Highway safety, Motor carriers.

Issued on: July 2, 1996.

Rodney E. Slater,

Federal Highway Administrator.

[FR Doc. 96–17420 Filed 7–8–96; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AC63

Endangered and Threatened Wildlife and Plants; Reopening of Comment Period on Proposed Endangered Status for Five Freshwater Mussels and Proposed Threatened Status for Two Freshwater Mussels From Eastern Gulf Slope Drainages of Alabama, Florida, and Georgia

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Fish and Wildlife Service provides notice that the comment period is reopened on a proposal to list the fat three-ridge, shiny-rayed pocketbook, Gulf moccasinshell, Ochlockonee moccasinshell, and oval pigtoe as endangered, and the Chipola slabshell and purple bankclimber as threatened, pursuant to the Endangered Species Act of 1973 (Act), as amended. The Service is reopening the comment period on this proposal to allow members of the public to submit comments on these proposals.

DATES: The comment period on this proposal is extended until July 26, 1996.

ADDRESSES: Written comments and materials concerning the proposal should be sent to the Field Supervisor, U.S. Fish and Wildlife Service, 6620 Southpoint Drive South, Suite 310, Jacksonville, Florida, 32216. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Robert S. Butler at the above address (telephone: 904/232–2580, fax 904/232–2404).

SUPPLEMENTARY INFORMATION:

Background

On August 3, 1994, the Service proposed to add seven freshwater mussels (fat three-ridge, shiny-rayed pocketbook, Gulf moccasinshell, Ochlockonee moccasinshell, oval pigtoe, Chipola slabshell, and purple bankclimber) to the list of endangered and threatened animals (59 FR 39524). These seven species are endemic to the Apalachicolan Region of the eastern Gulf Slope, defined as the rivers from the Escambia River in the west to the Suwannee River in the east. These drainages comprise southeast Alabama, southwest Georgia, and north Florida.

Section 4(b)(5)(E) of the Endangered Species Act of 1973, as amended, requires that a public hearing be held if it is requested within 45 days of the publication of a proposed rule. By September 19, 1994, the Service had received 12 public hearing requests on the proposal to list these seven mussels. The Service conducted five public informational meetings and five public hearings in January 1995. A notice of the public informational meetings, public hearings, and reopening of the comment period until February 10, 1995, was published in the Federal Register on December 12, 1994 (59 FR 63987). In a Federal Register notice appearing on April 24, 1995 (60 FR 20072), the Service extended the open comment period until May 5, 1995.

A moratorium on listing actions (Public Law 104–6) took effect April 10,

1995, and prevented the Service from making a final decision on these proposals by the August 1995 administrative deadline. The moratorium was lifted on April 26, 1996, when the appropriation for the Department of the Interior for the remainder of fiscal year 1996 was enacted into law. In a Federal Register document published on May 16, 1996 (61 FR 24722), the Service outlined in detail the history of the moratorium and indicated the priorities it would follow in eliminating the listing program backlog resulting from the moratorium. Preparation of final rules for these proposed species is considered a Tier 2 priority—processing final decisions on proposed listings. For more information on the moratorium and the priority for backlogged listing actions, refer to the May 15, 1996, Federal Register notice.

The Service hereby announces another reopening of the comment period until July 26, 1996. Reopening of the comment period will allow the Service to accept information on scientific studies conducted since the comment period last closed on May 5, 1995. Any other comments from the interested public will also be solicited concerning these proposals.

Author

The primary author of this notice is Robert S. Butler, Jacksonville Field Office, U.S. Fish and Wildlife Service, 6620 Southpoint Drive South, Suite 310, Jacksonville, Florida 32216 (904/232–2580 or fax 904/232–2404).

Authority: The authority for this action is the Endangered Species Act (16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500, unless otherwise noted).

Dated: July 1, 1996.

Noreen K. Clough,

Regional Director, Southeast Region, Fish and Wildlife Service.

[FR Doc. 96–17222 Filed 7–8–96; 8:45 am]

BILLING CODE 4310–55–P

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50 CFR Part 17

Endangered and Threatened Wildlife and Plants: 90-day Finding on a Petition to List the Santa Ana Speckled Dace, Santa Ana Sucker, and the Shay Creek Threespine Stickleback as Endangered

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of 90-day petition finding.

SUMMARY: The U. S. Fish and Wildlife Service (Service) announces a 90-day finding on a petition to list three fish as endangered, pursuant to the Endangered Species Act of 1973, as amended. The Service finds that the petition did not present substantial scientific or commercial information indicating the petitioned action may be warranted for two of the three species because it does not substantiate that the Santa Ana speckled dace and Shay Creek threespine stickleback are described subspecies or distinct vertebrate population segments as described in the Service's vertebrate population policy. Furthermore, the Service presently regards the Shay Creek threespine stickleback as a population of the unarmored threespine stickleback (*Gasterosteus aculeatus williamsoni*), a species that is already listed as endangered. Regarding the third fish species, the Service finds that substantial information exists to support a decision that listing may be warranted for the Santa Ana sucker.

DATES: The finding announced in this notice was made on June 28, 1996. Comments and materials may be submitted until further notice.

ADDRESSES: Data, information, comments, or questions concerning the finding should be submitted to the Field Supervisor, Carlsbad Field Office, U.S. Fish and Wildlife Service, 2730 Loker Avenue West, Carlsbad, California 92008. The petition, finding, and supporting data are available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Paul J. Barrett (see **ADDRESSES** above), telephone (619) 431–9440.

SUPPLEMENTARY INFORMATION:

Background

Section 4(b)(3)(A) of the Endangered Species Act (Act) of 1973, as amended (16 U.S.C. 1531 *et seq.*) requires that the Service make a finding on whether a petition to list, delist, or reclassify a species presents substantial scientific or commercial information indicating that the petitioned action may be warranted. To the maximum extent practicable, this finding is to be made within 90 days of the receipt of the petition, and the finding is to be published promptly in the Federal Register. This finding is based on information contained in the petition, supporting information submitted with the petition, and otherwise available to the Service at the time the finding is made. If the Service determines that the petitioned action may be warranted, the Service will commence a review of the status of the involved species. Status reviews will be commenced in accordance with priorities established by the Service pursuant to the May 16, 1996, Final Listing Priority Guidance (61 Fed Reg 24722).

On September 6, 1994, the Service received a petition dated September 2, 1994, to list the Santa Ana speckled dace (*Rhinichthys osculus* ssp.), Santa Ana sucker (*Catostomus santaanae*), and the Shay Creek threespine stickleback (*Gasterosteus aculeatus* ssp.) as endangered species. The petition was submitted by the Sierra Club Legal Defense Fund, Inc., on behalf of seven groups. The seven groups are the California-Nevada Chapter of the American Fisheries Society, The Nature School, The California Sportfishing Protection Alliance, Friends of the River, Izaak Walton League of America, California Trout, and Trout Unlimited. The letter clearly identified itself as a petition and contained the names, signatures, and addresses of the petitioners. Accompanying the petition was supporting information relating to taxonomy, ecology, and past and present distribution of all three species.

The petition, supporting documentation, and other information available in the Service files has been reviewed to determine if substantial information is available to indicate that the requested actions may be warranted. On the basis of the best scientific and commercial information available, the Service finds the petitioned action may be warranted for the Santa Ana sucker because of the threats to low population numbers, and is not warranted for the Santa Ana speckled dace based on taxonomic uncertainty. While the petitioners failed to present substantial information indicating that the Shay Creek threespine stickleback should be listed as a subspecies or distinct vertebrate population segment, the Shay Creek threespine stickleback is presently regarded as a population of the unarmored threespine stickleback and already receives the protections of the Act. A status review will be commenced in accordance with the Final Listing Priority Guidance for the Santa Ana sucker.

Santa Ana Sucker

The Santa Ana sucker (*Catostomus santaanae*) is a member of the sucker family (Catostomidae). The Santa Ana sucker was originally described as *Pantosteus santa-anae* by Snyder (1908, as in Moyle 1976). The genus *Pantosteus* was reduced to a subgenus of *Catostomus* and the hyphen omitted from the specific name in a subsequent revision of the nomenclature (Smith 1966). The American Fisheries Society

recognizes the Santa Ana sucker as the full species, *C. santaanae* (Robins et al. 1991).

The Santa Ana sucker's historical range includes the Los Angeles, San Gabriel, and Santa Ana River drainage systems located in southern California (Smith 1966). An introduced population also occurs in the Santa Clara River drainage system in southern California (Moyle 1976). Moyle and Yoshiyama (1992) state that only the San Gabriel River population can be considered relatively viable and self-sustaining within the native range.

Although the Santa Ana sucker was described as common in the 1970s (Moyle 1976), the species has experienced dramatic declines throughout most of its range (Moyle and Yoshiyama 1992). Santa Ana suckers have adaptations such as short generation time, high fecundity and a relatively prolonged spawning period that presumably allows them to rapidly repopulate streams after severe flooding events (Greenfield et al. 1970). Nevertheless, they are intolerant of polluted or highly modified streams (Moyle and Yoshiyama 1992).

This apparent, overall decline is of concern given this species' high fecundity and apparent broad habitat tolerances. Urbanization, water diversions, dams, pollution, heavy recreational use, gold mining wastes, gravel extraction, and introduced competitors and or predators have probably contributed in the decline of the species (Moyle and Yoshiyama 1992, Swift et al, 1993).

Swift (in Moyle and Yoshiyama 1992) summarized the status and threats facing each of the populations in their native range.

- Los Angeles River (Big Tujunga Creek below Big Tujunga Dam)—Extreme fluctuations in water quality pose problems for all fishes in this reach. The Santa Ana sucker is very rare and may already be lost here.
- San Gabriel River (contiguous West, North, and East forks about 40 km below Cogswell Dam)—The West Fork is threatened by accidental high flows from Cogswell Reservoir that have devastated this reach in the past. The Cattle Canyon tributary of the East Fork is impacted by increased gold mining (suction dredging) and the population has been much reduced or may be absent in Cattle Canyon.
- Santa Ana River—Several hundred fish were observed below Prado Dam in 1986 and 1987, although sampling above the dam in 1987 yielded only five Santa Ana suckers. Water quality is threatened by many and various local inputs, such as runoffs from light industry and surrounding farmed lands (T. Haglund, personal communication).

Subsequent to the receipt of the petition, a general fish survey of the Santa Ana River below Prado Dam yielded only 5 suckers from a total of approximately 150 fishes captured (Mike Guisti, California Game and Fish Department, pers. comm.). A survey of the East Fork of the San Gabriel River above the confluence with Cattle Canyon found the sucker to be relatively common, 125 of 382 fish captured (Paul Barrett, pers. obs., Fish and Wildlife Service files). The Santa Ana sucker's present status in the Los Angeles River is unknown.

The Service finds that the petitioners provided substantial evidence that the petitioned action may be warranted for the Santa Ana sucker.

Santa Ana Speckled Dace

The Santa Ana speckled dace is found in the headwaters of the Santa Ana and San Gabriel river drainages, often in isolated stocks. The petitioners presented a variety of information suggesting that the Santa Ana speckled dace is an undescribed subspecies of *Rhinichthys osculus*, member of the Cyprinidae family. While the petitioners assert that the Santa Ana speckled dace is a valid subspecies, they did not provide a peer-reviewed paper supporting that conclusion, nor did they provide a draft manuscript that the Service could subject to peer review. In fact, citing Moyle (1976), the petitioners actually point out difficulties with speckled dace systematics, ''Although systematists now seem to have little trouble placing the many forms into *Rhinichtys osculus* (Hubbs, Miller, and Hubbs, 1974), the status of the many described (and undescribed) subspecies can only be called chaotic.'' The primary support for subspecific status includes reference to a Master's thesis (Cornelius 1969) which was not included with the petition, and reference to unpublished genetic data. Other, anecdotal evidence supporting subspecific status includes a species account written by C.C. Swift that was included as pages 207–212 in a document entitled Fishes, Aquatic Diversity Management Areas, and Endangered Species: A Plan to Protect California's native Aquatic Biota, edited by Moyle and Yoshiyama (1992). This account cites a paper by Hubbs et al. (1979) that includes the Santa Ana speckled dace as an unnamed subspecies, but a copy of the paper was not provided and the literature cited section of the account did not include a citation that would allow the Service to identify the paper.

Shay Creek Threespine Stickleback

The petitioners indicated that the Shay Creek threespine stickleback is an undescribed form of the threespine stickleback (*Gasterosteus aculeatus*) that should be listed separately from the endangered unarmored threespine stickleback. The Service regards the Shay Creek threespine stickleback as a population of the Federally listed unarmored threespine stickleback and the petitioners failed to present substantiated scientific information indicating that the petitioned action may be warranted. Specifically, the petitioners did not present peer-reviewed information supporting their claim that the Shay Creek threespine stickleback is a separate subspecies or distinct vertebrate population. In light of this decision and until the Service is presented with substantiated information to the contrary, the Shay Creek threespine stickleback remains a population of the Federally endangered unarmored threespine stickleback.

It is Service policy to issue not-substantial 90-day findings on petitions for species or subspecies if that designation has not passed scientific peer review either as part of acceptance for publication or through some other equivalent review. The Santa Ana speckled dace and Shay Creek threespine stickleback are not so named. Should the Santa Ana speckled dace or Shay Creek threespine stickleback be determined to be a valid subspecies as evidenced by a description in a peer-reviewed scientific journal, or a distinct population segment in accord with the February 7, 1996, ''Recognition of Distinct Vertebrate Population Segments Under the Endangered Species Act '' (61 FR 4722), the Service may consider a proposal to list this species in accordance with the Service's listing priority guidance. In addition to taxonomic information, any new petition should clearly identify threats to the taxa, including estimates of the probability of catastrophic events to the populations.

The Service will continue to seek information regarding the Santa Ana speckled dace. As additional data becomes available in the future, the Service may reassess the need for preparing a proposal to list this species, in accordance with the final Listing Priority Guidance.

Conformance with Listing Priority Guidance

On May 16, 1996 the Service published a description of how it will prioritize the various listing actions for the remainder of fiscal year 1996 (61 FR

24722–24728). Based on the listing priority guidance, the subject finding would characteristically have been assigned to tier 3 and processing would have been delayed until a later date. Despite requests for deference to the listing priority guidance, however, the Service has received no relief and is compelled by court order to issue this finding.

References Cited

Buth, D. G. and C. B. Crabtree. 1982. Genetic variability and population structure of *Catostomus santaanae* in the Santa Clara drainage. Copeia, 1982:439–444.

Greenfield, D. W., S. T. Ross, and G. D. Deckert. 1970. Some aspects of the life history of the Santa Ana sucker, Catostomus (Pantosteus) santaanae (Snyder). California Fish and Game 56:166–179.

Haglund, T. A. and D. G. Buth. 1988. Allozymes of the unarmored threespine stickleback (Gasterosteus aculeatus williamsoni) and identification of the Shay Creek population. Isozyme Bulletin, 21:196.

Hubbs, W. I. Follett, and L. C. Hubbs. 1979. List of fishes of California. Occasional Papers of the California Academy of Sciences, No. 133, 51 pp.

Moyle, P. B. 1976. Inland Fishes of California. University of California Press, 405 pp.

Moyle, P. B. and R. M. Yoshiyama. 1992. Fishes, aquatic diversity management areas, and endangered species: Plan to protect California's native aquatic biota. The California Policy Seminar, University of California.

Robins, C. R., R. M. Baily, C. E. Bond, J. R. Brooker, E. A. Lachner, R. N. Lea, and W. B. Scott. 1991. Common and scientific names of fishes of the United States and Canada. American Fisheries Society Special Publication 20. Bethesda, Maryland.

Swift, C. C., T. R. Haglund, M. Ruiz, and R. N. Fisher. 1993. The status and distribution of the freshwater fishes of southern California. Bulletin of the Southern California Academy of Sciences, 92:1–67.

Author

This notice was prepared by Paul J. Barrett, Carlsbad Field Office (see **ADDRESSES** section above).

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 et seq.).

Dated: June 28, 1996.

John G. Rogers,

Acting Director, Fish and Wildlife Service.

[FR Doc. 96–17390 Filed 7–8–96; 8:45 am]

BILLING CODE 4310–55–P

Notices

Federal Register
Vol. 61, No. 132
Tuesday, July 9, 1996

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

Notice of Intent to prepare an Environmental Impact Statement (EIS)

SUMMARY: The Salt Lake Ranger District, of the Wasatch-Cache National Forest, will prepare an EIS on Brighton Ski Resort's (Brighton) proposal to update their Master Development Plan.

DATES: Comments concerning the scope of the analysis should be received in writing by August 9, 1996.

ADDRESSES: Send written comments to Michael Sieg, District Ranger, 3000 East 6944 South, Salt Lake City, Utah 84121.

FOR FURTHER INFORMATION CONTACT: Steve Scheid, Environmental Analyst, (801) 943–9483.

SUPPLEMENTARY INFORMATION: Brighton is proposing to update their Master Development Plan. This update includes the following elements: upgrade the Snake Creek lift to a high-speed detachable Quad, construct a new transportation lift between Solitude Ski Resort and Brighton, modify existing ski trails, which include rock and stump removal and terrain grading, expand night skiing opportunities, construct new mid-mountain lodge at the base of the Snake Creek Lift, expand current snowmaking facilities, and expand the existing hiking and biking trail systems. A complete description of the proposal and its elements is available from the Salt Lake Ranger District.

Brighton will be required to obtain an amendment of water supply permit agreement from Salt Lake City Department of Public Utilities and a Water Change Application from the Utah Department of Natural Resources, Division of Water Rights, State Engineer. They will also be required to obtain all necessary building and construction permits from Salt Lake County.

A scoping document has been sent to more than 600 individuals, organizations and government agencies, detailing Brighton's proposal for the next planning period. Preliminary issues identified by the interdisciplinary team include effects of the proposed action on: visual quality, run quality, year-round recreation experiences, wetland and riparian areas, water quality and quantity, vegetation, fish and wildlife, traffic and parking in Big Cottonwood Canyon, and threatened, endangered and sensitive species.

Two preliminary alternatives have been identified: (1) the proposed action which would permit the aforementioned projects and require Brighton to convert to a new Ski Area Term Special Use Permit, and (2) the No Action alternative which would continue the use as currently permitted with no new improvements.

The public is invited to submit comments or suggestions to the address above. This public comment period does not replace the initial public comment period. All comments received to date will be included in the EIS. We are seeking new issues, comments and suggestions. The responsible official is Bernie Weingardt, Forest Supervisor. A draft EIS is expected to be filed in May, 1997 and the final EIS filed in September 1997.

The comment period on the draft EIS 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 that time. To be the most helpful, comments on the draft EIS 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 draft EIS's must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviews' position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC,* 435 U.S. 519, 533 (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. *City of Angoon* v. *Hodel*, (9th Circuit, 1986) and *Wisconsin Heritages, 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: July 2, 1996.

Steven W. Scheid,

District Environmental Analyst.

[FR Doc. 96–17445 Filed 7–8–96; 8:45 am]

BILLING CODE 3410–11–M

Rural Utilities Service

Information Collection Activity; Comment Request

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended), the Rural Utilities Service's (RUS) invites comments on this information collection for which RUS intends to request approval from the Office of Management and Budget (OMB).

DATES: Comments on this notice must be received by September 9, 1996.

FOR FURTHER INFORMATION CONTACT: Billy J. Chapman, Loan Specialist, Processing Division, Water and Waste Disposal, Rural Utilities Service, U.S. Department of Agriculture, 14th & Independence Ave., SW., AG Box 3223, Washington, DC 20250–1500. Telephone: (202) 690–3789. FAX: (202) 690–0649.

SUPPLEMENTARY INFORMATION:

Title: 7 CFR 1942–I, Resources Conservation and Development.

OMB Control Number: 0572–0111.

Type of Request: Extension of a Currently Approved Information Collection.

Abstract: This program would provide loan assistance to sponsoring local organizations (public and nonprofit) in authorized watershed areas for the local share of cost for works of improvement. RUS will assist the local sponsors and the Soil Conservation Service (SCS) in making loans for the development of future water supplies or for site preservation.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 3.5 hours per response.

Respondents: State or local governments, small business or organizations, and non-profit institutions.

Estimated Number of Respondents: 2.

Estimated Number of Responses per Respondent: 8.

Estimated Total Annual Burden on Respondents: 56.

Copies of this information collection, and related form and instructions, can be obtained from Dawn Wolfgang, Program Support and Regulatory Analysis Group, at (202) 720–0812.

Comments are invited on: (a) Whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments may be sent to: F. Lamont Heppe, Jr., Director, Program Support and Regulatory Analysis Group, Rural Utilities Service, U.S. Department of Agriculture, AG Box 1522, 14th & Independence Ave., SW., Washington, DC 20250–1522. FAX: (202) 720–4120.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record:

Dated: June 28, 1996.

John P. Romano,

Acting Administrator, Rural Utilities Service.

[FR Doc. 96–17363 Filed 7–8–96; 8:45 am]

BILLING CODE 3410–15–M

DEPARTMENT OF COMMERCE

Office of the Secretary

Submission for OMB Review: Comment Request

DOC has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: Patent and Trademark Office (PTO).

Title: Admittance to Practice and Roster of Registered Patent Attorneys and Agents Admitted to Practice Before the Patent and Trademark Office.

Agency Approval Number: 0651–0012.

Type of Request: Extension of the expiration date of a currently approved collection without any change in the substance or in the method of collection.

Burden: 3,500 hours.

Number of Respondents: 10,500.

Avg. Hours Per Response: ⅓ hour.

Needs and Uses: Information is required to determine the qualifications of individuals entitled to represent applicants before the Patent and Trademark Office in the preparation and prosecution of applications for a patent, and to administer and maintain the roster of attorneys registered to practice before the Patent and Trademark Office.

Affected Public: Individuals.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain a benefit.

OMB Desk Officer: Maya A. Bernstein, (202) 395–4816.

Copies of the above information collection proposal can be obtained by calling or writing Linda Engelmeier, Acting DOC Forms Clearance Officer, (202) 482–3272, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW, Washington, D.C. 20230.

Written comments and recommendations for the proposed information collection should be sent to Maya A. Bernstein, OMB Desk Officer, Room 10236, New Executive Office building, Washington, D.C. 20503.

Dated: July 3, 1996.

Linda Engelmeier,

Acting Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 96–17449 Filed 7–08–96; 8:45 am]

BILLING CODE 3510–16–P

International Trade Administration

[A–570–808]

Chrome-Plated Lug Nuts From The People's Republic of China; Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of Preliminary Results of the Antidumping Duty Administrative Review of Chrome-Plated Lug Nuts from the People's Republic of China.

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on chrome-plated lug nuts (lug nuts) from the People's Republic of China (PRC) in response to a request by petitioner, Consolidated International Automotive, Inc. (Consolidated). This review covers shipments of this merchandise to the United States during the period September 1, 1994, through August 31, 1995.

We have preliminarily determined that sales have been made below normal value (NV). If these preliminary results are adopted in our final results, we will instruct the U.S. Customs Service to assess antidumping duties equal to the difference between export price and NV.

Interested parties are invited to comment on these preliminary results. Parties who submit argument are requested to submit with each argument (1) a statement of the issue and (2) a brief summary of the argument.

EFFECTIVE DATE: July 9, 1996.

FOR FURTHER INFORMATION CONTACT: Donald Little, Elisabeth Urfer, or Maureen Flannery, Office of Antidumping Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington D.C. 20230; telephone (202) 482–4733.

Applicable Statute

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930 (the Act) by the Uruguay Round Agreements Act (URAA). In addition, unless otherwise indicated, all citations to the Department's regulations are to the current regulations, as amended by the interim regulations published in the Federal Register on May 11, 1995 (60 FR 25130).

Background

The Department published in the Federal Register an antidumping duty order on lug nuts from the PRC on April 24, 1992 (57 FR 15052). On September 12, 1995, the Department published in the Federal Register (60 FR 47349) a notice of opportunity to request an administrative review of the antidumping duty order on lug nuts from the PRC covering the period September 1, 1994, through August 31, 1995.

On September 28, 1995, in accordance with 19 CFR 353.22(a), Consolidated requested that we conduct an administrative review of China National Automotive Industry I/E Corp., Nantong

Branch (Nantong); China National Automobile Import and Export Corp., Yangzhou Branch (Yangzhou); Jiangsu Rudong Grease-Gun Factory, also known as JiangSu Huanghai Auto Parts Share Co., Ltd. (Rudong); Ningbo Knives & Scissors Factory (Ningbo); Shanghai Automobile Import & Export Corp. (Shanghai Automobile); Tianjin Automotive Import and Export Co. (Tianjin); China National Machinery & Equipment Import & Export Corp., Jiangsu Branch (Jiangsu); and China National Automotive Industry I/E Corp. (China National). We published a notice of initiation of this antidumping duty administrative review on October 12, 1995 (60 FR 53165). The Department is conducting this administrative review in accordance with section 751 of the Act.

Scope of Review

On April 19, 1994, the Department issued its ''Final Scope Clarifications on Chrome-Plated Lug Nuts from Taiwan and the PRC.'' The scope, as clarified, is described in the subsequent paragraph. All lug nuts covered by this review conform to the April 19, 1994 scope clarification.

Imports covered by this review are one-piece and two-piece chrome-plated lug nuts, finished or unfinished. The subject merchandise includes chrome-plated lug nuts, finished or unfinished, which are more than 11/16 inches (17.45 millimeters) in height and which have a hexagonal (hx) size of at least 3/4 inches (19.05 millimeters) but not over one inch (25.4 millimeters), plus or minus 1/16 of an inch (1.59 millimeters). The term ''unfinished'' refers to unplated and/or unassembled chrome-plated lug nuts. The subject merchandise is used for securing wheels to cars, vans, trucks, utility vehicles, and trailers. Zinc-plated lug nuts, finished or unfinished, and stainless-steel capped lug nuts are not included in the scope of this review. Chrome-plated lock nuts are also not subject to this review.

Chrome-plated lug nuts are currently classified under subheading 7318.16.00.00 of the Harmonized Tariff Schedule (HTS). Although the HTS subheading is provided for convenience and customs purposes, the written description of the scope of this proceeding is dispositive.

This review covers the period September 1, 1994, through August 31, 1995, and eight producers/exporters of Chinese lug nuts.

Market-Oriented Industry

In every case conducted by the Department involving the PRC, the PRC has been treated as a non-market economy (NME) country. Pursuant to section 771(18)(c)(i) of the Act, any determination that a foreign country is an NME country shall remain in effect until revoked by the administering authority. Information presented in this review has not caused the Department to change that determination.

Rudong submitted, with its January 25, 1996 questionnaire response, a request that we treat the lug nuts industry as a market-oriented industry (MOI). Rudong claims that its material inputs are acquired at market prices and that, accordingly, we should find that the Chinese lug nuts industry is an MOI, and use Rudong's home market sales and/or costs as the basis of NV.

The criteria for determining whether an MOI exists are: 1) for the merchandise under review, there must be virtually no government involvement in setting prices or amounts to be produced; 2) the industry producing the merchandise under review should be characterized by private or collective ownership; and 3) market-determined prices must be paid for all significant inputs, whether material or non-material (*e.g.*, labor and overhead), and for all but an insignificant portion of all the inputs accounting for the total value of the merchandise under review. (*See Amendment to Final Determination of Sales at Less than Fair Value and Amendment to Antidumping Duty Order: Chrome-Plated Lug Nuts from the People's Republic of China* (57 FR 15054, April 24, 1992) (*Lug Nuts Redetermination*).)

We find preliminarily in this review that the PRC lug nut industry does not meet these three criteria. With respect to the first and second criteria, Rudong has stated that it is the only producer of lug nuts, that it is a collectively-owned public enterprise, and that it independently negotiates prices. However, we did not receive a PRC government response to our questionnaire requesting the names of all lug nut producers in the PRC. We were unable, therefore, to determine whether the first and second criteria are met for the industry as a whole. With respect to the third criterion, Rudong did not submit any information on supply and demand factors indicating that it pays market-determined prices for steel, a major input in lug nut production, or that the steel industry is not subject to significant state control. Further, Rudong has not placed on the record any information on supply and demand factors indicating that it pays market-determined prices for chemical inputs, or that the chemicals industry is not subject to significant state control. Based on the foregoing, we preliminarily determine that Rudong has not demonstrated the lug nut industry is an MOI and accordingly have calculated NV in accordance with section 773(c) of the Act. For a further discussion of the Department's preliminary determination that the lug nuts industry does not constitute an MOI, see *Decision Memorandum to Holly A. Kuga, Director of the Office of Antidumping Compliance,* dated June 18, 1996, ''Market Oriented Industry Request in the Third Administrative Review of Chrome-Plated Lug Nuts from the People's Republic of China,'' which is on file in the Central Records Unit (room B099 of the Main Commerce Building).

Facts Available

We preliminarily determine that, in accordance with section 776(a) of the Act, the use of facts available is appropriate for Nantong, Yangzhou, Ningbo, Jiangsu, China National, Tianjin, and Shanghai Automobile because these firms did not respond to the Department's antidumping questionnaire. The Department finds that, in not responding to the questionnaire, these seven firms failed to cooperate by not acting to the best of their ability to comply with requests for information from the Department. Because necessary information is not available on the record with regard to sales by these firms as a result of their withholding the requested information, we must make our preliminary determination based on facts otherwise available pursuant to section 776(a) of the Act.

Where the Department must base the entire dumping margin for a respondent in an administrative review on the facts available because that respondent failed to cooperate, section 776(b) authorizes the Department to use an inference adverse to the interests of that respondent in choosing the facts available. Section 776(b) also authorizes the Department to use as adverse facts available information derived from the petition, the final determination, a previous administrative review, or other information placed on the record. Because information from prior proceedings constitutes secondary information, section 776(c) provides that the Department shall, to the extent practicable, corroborate that secondary information from independent sources reasonably at its disposal. The Statement of Administrative Action (SAA) provides that ''corroborate'' means simply that the Department will satisfy itself that the secondary

information to be used has probative value.

To corroborate secondary information, the Department will, to the extent practicable, examine the reliability and relevance of the information to be used. However, unlike other types of information, such as input costs or selling expenses, there are no independent sources for calculated dumping margins. The only source for margins is administrative determinations. Thus, in an administrative review, if the Department chooses as total adverse facts available a calculated dumping margin from a prior segment of the proceeding, it is not necessary to question the reliability of the margin for that time period. With respect to the relevance aspect of corroboration, however, the Department will consider information reasonably at its disposal as to whether there are circumstances that would render a margin not relevant. Where circumstances indicate that the selected margin is not appropriate as adverse facts available, the Department will disregard the margin and determine an appropriate margin (*see, e.g., Fresh Cut Flowers from Mexico; Preliminary Results of Antidumping Duty Administrative Review* (60 FR 49567, September 26, 1995), where the Department disregarded the highest margin as adverse best information available because the margin was based on another company's uncharacteristic business expense resulting in an unusually high margin). In this case, we have used the highest rate from any prior segment of the proceeding, 44.99 percent. There is no indication that this rate is not appropriate. This rate was calculated in the review covering the period September 1, 1992 through August 31, 1993 (1992–1993 review).

Separate Rates

To establish whether a company operating in a state-controlled economy is sufficiently independent to be entitled to a separate rate, the Department analyzes each exporting entity under the test established in the *Final Determination of Sales at Less Than Fair Value: Sparklers from the People's Republic of China* (56 FR 20588, May 6, 1991) (*Sparklers*), as amplified by the *Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the People's Republic of China* (59 FR 22585, May 2, 1994) (*Silicon Carbide*). Under this policy, exporters in non-market economies (NMEs) are entitled to separate, company-specific margins when they can demonstrate an absence of government control, both in law and in fact, with respect to export activities. Evidence supporting, though not requiring, a finding of *de jure* absence of government control over export activities includes: 1) an absence of restrictive stipulations associated with an individual exporter's business and export licenses; 2) any legislative enactments decentralizing control of companies; and 3) any other formal measures by the government decentralizing control of companies. *De facto* absence of government control over exports is based on four factors: 1) whether each exporter sets its own export prices independently of the government and without the approval of a government authority; 2) whether each exporter retains the proceeds from its sales and makes independent decisions regarding the disposition of profits or financing of losses; 3) whether each exporter has the authority to negotiate and sign contracts and other agreements; and 4) whether each exporter has autonomy from the government regarding the selection of management.

In the administrative review covering the period from September 1, 1992 through August 31, 1993 (1992–93 review), we determined that Nantong merited a separate rate, and in the 1993–94 review we preliminary determined that Rudong merited a separate rate. Because we made a final determination, under the criteria set forth in *Sparklers* and *Silicon Carbide*, that Nantong merited a separate rate, and therefore did not request that Nantong respond to the separate rates section of the questionnaire, and because no evidence was put on the record of this review demonstrating that Nantong did not merit a separate rate, for this review we continue to assign Nantong a separate rate. (As noted above, this rate is based on facts available.) Because the results from the 1993–94 review are not final, we analyzed Rudong's submission in this review to determine whether Rudong merits a separate rate. We have made the determination of whether Rudong should receive a separate rate under the policy set forth in *Silicon Carbide* and *Sparklers*. No other company in this review was previously determined to merit a separate rate under the *Sparklers* and *Silicon Carbide* criteria, or responded to our request for information regarding separate rates; therefore, we are assigning the PRC rate to these remaining companies.

With respect to the absence of *de jure* government control, evidence on the record indicates that Rudong is a collectively-owned enterprise. The ''Regulations on Rural Collective Enterprises'' identify rules and regulations pertaining to collectively-owned enterprises which give rural collective enterprises such rights as the right to act on their own, adopt independent accounting, and assume the sole responsibility for their profits and losses. (*See* May 31, 1996 memorandum to the file, with attachments, ''Chrome-Plated Lug Nuts from the People's Republic of China: laws and regulations governing various categories of companies in the PRC.'')

Further, several PRC laws establish that the responsibility for managing entities has been transferred from the central government to the enterprise. (*See* July 18, 1995 memorandum to the file, with attachments, ''Chrome-Plated Lug Nuts from the People's Republic of China: laws and regulations governing various categories of companies in the PRC.'') Additionally, lug nuts do not appear on the ''Temporary Provisions for Administration of Export Commodities,'' approved on December 21, 1992, and are not, therefore, subject to the constraints of this provision.

With respect to the absence of *de facto* control, Rudong's management is elected by Rudong's staff, and is responsible for all decisions such as the determination of its export prices, profit distribution, employment policy, and marketing strategy, and for negotiating contracts.

We have found that the evidence on the record demonstrates an absence of government control, both in law and in fact, with respect to Rudong according to the criteria identified in *Sparklers* and *Silicon Carbide*. For further discussion of the Department's preliminary determination that Rudong is entitled to a separate rate, *see Decision Memorandum to Holly A. Kuga, Director of the Office of Antidumping Compliance*, dated June 18, 1996, ''Separate Rate for Jiangsu Rudong Grease-Gun Factory in the Fourth Administrative Review of Chrome-Plated Lug Nuts from the People's Republic of China,'' which is on file in the Central Records Unit (room B099 of the Main Commerce Building).

Export Price

For sales made by Rudong we used export price, in accordance with section 772(a) of the Act, because the subject merchandise was sold to unrelated purchasers in the United States prior to importation into the United States.

We calculated export price based on the price to unrelated purchasers. We deducted an amount for foreign inland freight. We valued foreign inland freight using surrogate data based on Indian freight costs. We selected India as the

surrogate country for the reasons explained in the ''Normal Value'' section of this notice.

Normal Value

For companies located in NME countries, section 773(c)(1) of the Act provides that the Department shall determine NV using a factors-of-production methodology if (1) the merchandise is exported from an NME country, and (2) the information does not permit the calculation of NV using home-market prices, third-country prices, or constructed value under section 773(a) of the Act.

In the amendment to the final determination of sales at less than fair value (LTFV), the Department treated the PRC as an NME country, and determined that the lug nuts industry is not an MOI (*see Lug Nuts Redetermination*). Rudong has argued that the lug nut industry is an MOI; however, as discussed above, we have preliminarily determined the lug nut industry not to be market-oriented. Accordingly, we are not able to determine NV on the basis of Rudong's costs and prices, and have applied surrogate values to the factors of production to determine NV.

We calculated NV based on factors of production in accordance with section 773(c)(4) of the Act and section 353.52(c) of our regulations. We determined that India (1) is comparable to the PRC in terms of level of economic development, and (2) is a significant producer of comparable merchandise. Therefore, for this review, we have used publicly available information relating to India to value the various factors of production. (*See Memorandum to Laurie Parkhill from David Mueller,* dated March 15, 1996, ''Chrome-Plated Lug Nuts from the People's Republic of China: Non-market Economy Status and Surrogate Country Selection,'' and *Memorandum to the File from Elisabeth Urfer,* dated June 14, 1996, ''India: Significant Production of Comparable Merchandise,'' which are on file in the Central Records Unit (room B099 of the Main Commerce Building).)

We valued the factors of production as follows:

- For steel wire rods, we used a per kilogram value obtained from the *Monthly Statistics of Foreign Trade of India* (*Indian Import Statistics*). Using wholesale price indices (WPI) obtained from the *International Financial Statistics*, published by the International Monetary Fund (IMF), we adjusted these values to reflect inflation through the period of review (POR). We made further adjustments to include freight costs incurred between the supplier and Rudong.
- For chemicals used in the production and plating of lug nuts, we used per kilogram values obtained from the Indian publication *Chemical Weekly* and the *Indian Import Statistics.* We adjusted the *Indian Import Statistics* rates to reflect inflation through the POR using WPI published by the IMF. We made further adjustments to include freight costs incurred between the supplier and Rudong.
- For hydrochloric acid, we based the value on an Indian price quote used in the *Final Determination of Sales at Less Than Fair Value: Coumarin from the People's Republic of China* (59 FR 66895, December 28, 1994) (*Coumarin*), because data in the *Indian Import Statistics* for hydrochloric acid has been found to be aberrational (*see Coumarin*). We adjusted the value used in *Coumarin* to reflect inflation through the POR using WPI published by the IMF.
- For direct labor, we used the labor rates reported in the Economic Intelligence Unit report *Investing, Licensing & Trading Conditions Abroad: India,* released November 1994. This source breaks out labor rates between skilled and unskilled labor for 1994 and provides information on the number of labor hours worked per week. We adjusted these rates to reflect inflation through the POR using WPI published by the IMF.
- For factory overhead, we used information reported in the April 1995 *Reserve Bank of India Bulletin* for the Indian metals and chemicals industries. From this information, we were able to determine factory overhead as a percentage of the total cost of manufacture.
- For selling, general and administrative (SG&A) expenses, we used information obtained from the April 1995 *Reserve Bank of India Bulletin* for the Indian metals and chemicals industries. We calculated an SG&A rate by dividing SG&A expenses by the cost of manufacture.
- To calculate a profit rate, we used information obtained from the April 1995 *Reserve Bank of India Bulletin* for the Indian metals and chemicals industries. We calculated a profit rate by dividing the before-tax profit by the cost of manufacturing plus SG&A.
- For packing materials, we used per kilogram values obtained from the *Indian Import Statistics.* We adjusted these values to reflect inflation through the POR using WPI published by the IMF.
- To value electricity, we used the average price of electricity as of March 1995 published in the *Current Energy Scene in India.* We adjusted the value of electricity to reflect inflation through the POR using WPI published by the IMF.
- To value truck freight, we used the rates reported in an August 1993 cable from the U.S. Consulate in India submitted for the *Final Determination of Sales at Less Than Fair Value: Certain Helical Spring Lock Washers From the People's Republic of China* (58 FR 48833, September 20, 1993). We adjusted the rates to reflect inflation through the POR using WPI published by the IMF.

Currency Conversion

We made currency conversions pursuant to section 353.60 of the Department's regulations at the rates certified by the Federal Reserve Bank.

Preliminary Results of Review

We preliminarily determine that the following dumping margin exists:

Manufacturer/exporter	Time period	Margin (percent)
Jiangsu Rudong Grease-Gun Factory, also known as JiangSu Huanghai Auto Parts Share Co., Ltd.	09/01/94–08/31/95	20.11
China National Automotive Industry I/E Corp., Nantong Branch	09/01/94–08/31/95	44.99
PRC rate	09/01/94–08/31/95	44.99

Parties to the proceeding may request disclosure within 5 days of the date of publication of this notice in accordance with 19 CFR 353.22(c)(6). Any interested party may request a hearing within 10 days of publication in accordance with 19 CFR 353.38(b). Any hearing, if requested, will be held 44 days after the publication of this notice, or the first workday thereafter. Interested parties may submit case briefs within 30 days of the date of publication of this notice in accordance with 19 CFR 353.38(c). Rebuttal briefs, which must be limited to issues raised in the case

briefs, may be filed not later than 37 days after the date of publication. The Department will publish a notice of final results of this administrative review, which will include the results of its analysis of issues raised in any such comments.

The Department shall determine, and the U.S. Customs Service shall assess, antidumping duties on all appropriate entries. Individual differences between export price and NV may vary from the percentage stated above. The Department will issue appraisement instructions directly to the U.S. Customs Service.

Furthermore, the following deposit rates will be effective upon publication of the final results of this administrative review for all shipments of lug nuts from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) for Rudong, which has a separate rate, the cash deposit rate will be the company-specific rate established in the final results of this administrative review; (2) for Nantong, which has a separate rate, the cash deposit rate will be the highest margin ever in the LTFV investigation or in this or prior administrative reviews; (3) for the companies named above which have not been found to have separate rates, China National, Jiangsu, Yangzhou, Ningbo, Shanghai Automobile, and Tianjin, as well as for all other PRC exporters, the cash deposit rate will be the PRC rate; and (4) for non-PRC exporters of subject merchandise from the PRC, the cash deposit rate will be the rate applicable to the PRC supplier of that exporter.

These deposit rates, when imposed, shall remain in effect until publication of the final results of the next administrative review.

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 353.26 to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This administrative review and notice are in accordance with section 751(a)(1) of the Act (19 U.S.C. 1675(a)(1)) and 19 CFR 353.22.

Dated: July 1, 1996.

Robert S. LaRussa,

Acting Assistant Secretary for Import Administration.

[FR Doc. 96–17463 Filed 7–8–96; 8:45 am]

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[A–580–812]

Dynamic Random Access Memory Semiconductors of One Megabit or Above from the Republic of Korea; Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Preliminary Results of Antidumping Duty Administrative Review.

SUMMARY: In response to requests from three respondents and one U.S. producer, the Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on dynamic random access memory semiconductors of one megabit or above from the Republic of Korea. The review covers two manufacturers/exporters of the subject merchandise to the United States for the period of May 1, 1994 through April 30, 1995. The review indicates that there are no dumping margins for either manufacturer/exporter during this period of review.

If these preliminary results are adopted in our final results of administrative review, we will instruct the U.S. Customs Service to assess antidumping duties equal to the difference between the United States price and the normal value (NV). Interested parties are invited to comment on these preliminary results. Parties who submit arguments in this proceeding are requested to submit with the argument (1) a statement of the issue, and (2) a brief summary of the argument.

EFFECTIVE DATE: July 9, 1996.

FOR FURTHER INFORMATION CONTACT: Thomas F. Futtner, Office of Antidumping Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230, telephone: (202) 482–3814.

SUPPLEMENTARY INFORMATION:

Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930 (the Act) by the Uruguay Round Agreements Act (URAA). In addition, unless otherwise indicated, all citations to the Department's regulations are to the current regulations, as amended by the interim regulations published in the Federal Register on May 11, 1995 (60 FR 25130).

Background

On May 10, 1993, the Department published in the Federal Register (58 FR 27250) the antidumping duty order on dynamic random access memory semiconductors (DRAMS) from the Republic of Korea. On May 10, 1995, the Department published a notice of ''Opportunity to Request an Administrative Review'' of this antidumping duty order for the period of May 1, 1994, through April 30, 1995 (60 FR 24831). We received timely requests for review from three manufacturers/exporters of subject merchandise to the United States: Hyundai Electronics Industries Co. (Hyundai), LG Semicon Co., Ltd. (LGS, formerly Goldstar Electron Co., Ltd.), and Samsung Electronics Co. (Samsung). The petitioner, Micron Technologies Inc., requested an administrative review of these same three Korean manufacturers of DRAMS. On June 15, 1995, the Department initiated a review of the above Korean manufacturers (60 FR 31447). The period of review (POR) for all respondents was May 1, 1994, through April 30, 1995. The Department has now conducted this review in accordance with section 751 of the Act.

In addition, on June 26, 1995, we automatically initiated an investigation to determine if Hyundai and LGS made sales of subject merchandise below the cost of production (COP) during the POR based upon the fact that we disregarded sales found to have been made below the COP in the original less-than-fair-value (LTFV) investigation, which was the most recent period for which a review had been completed.

Samsung Electronics Co., Ltd. (Samsung), formerly a respondent in this administrative review, was excluded from the antidumping duty order on DRAMS from Korea on February 8, 1996. *See Final Court Decision and Partial Amended Final Determination: Dynamic Random Access Memory Semiconductors of One Megabit and Above From the Republic of Korea,* 61 FR 4765 (February 8, 1996). Accordingly, we terminated this review with respect to Samsung.

Scope of the Review

Imports covered by the review are shipments of DRAMs of one megabit or above from the Republic of Korea (Korea). For purposes of this review, DRAMS are all one megabit and above DRAMS, whether assembled or unassembled. Assembled DRAMS include all package types. Unassembled DRAMS include processed wafers, uncut die and cut die. Processed wafers produced in Korea, but packaged, or assembled into memory modules in a third country, are included in the scope; wafers produced in a third country and assembled or packaged in Korea are not included in the scope.

The scope of this review includes memory modules. A memory module is a collection of DRAMS, the sole function of which is memory. Modules include single in-line processing modules (SIPs), single in-line memory modules (SIMMs), or other collections of DRAMS, whether unmounted or mounted on a circuit board. Modules that contain other parts that are needed to support the function of memory are covered. Only those modules which contain additional items which alter the function of the module to something other than memory, such as video graphics adapter (VGA) boards and cards, are not included in the scope.

The scope of this review also includes video random access memory semiconductors (VRAMS), as well as any future packaging and assembling of DRAMS.

The scope of this review also includes removable memory modules placed on motherboards, with or without a central processing unit (CPU), unless the importer of motherboards certifies with the Customs Service that neither it, nor a party related to it or under contract to it, will remove the modules from the motherboards after importation. The scope of this review does not include DRAMS or memory modules that are reimported for repair or replacement.

The DRAMS subject to this review are classifiable under subheadings 8542.11.0001, 8542.11.0024, 8542.11.0026, and 8542.11.0034 of the Harmonized Tariff Schedule of the United States (HTSUS). Also included in the scope are those removable Korean DRAMS contained on or within products classifiable under subheadings 8471.91.0000 and 8473.30.4000 of the HTSUS. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this review remains dispositive. The POR is May 1, 1994, through April 30, 1995.

United States Price

In calculating U.S. price, the Department used constructed export price (CEP), as defined in section 772(b) of the Act, when the merchandise was first sold to an unaffiliated U.S. purchaser after importation.

We calculated CEP based on packed, ex-U.S. warehouse prices to unrelated customers in the United States. We made deductions, where appropriate, for discounts, rebates, foreign brokerage and handling, foreign inland insurance, air freight, air insurance, U.S. duties, credit expenses, warranty expenses, royalty payments, U.S. commissions, advertising and promotion expenses, foreign banking charges, U.S. subsidiary packing, and U.S. and Korean indirect selling expenses, including inventory carrying costs in accordance with sections 772(c)(2) and 772(d)(1) of the Act. The U.S. price was increased for packing expense in accordance with section 772(c)(1) of the Act. We added duty drawback, where applicable, pursuant to section 772(c)(1)(B) of the Act. Pursuant to section 772(d)(3) of the Act, we reduced the United States price by the amount of profit to derive the CEP.

For DRAMS that were further manufactured into memory modules after importation, we deducted all value added in the United States, pursuant to section 772(e) of the Act. The value added consists of the costs of the materials, fabrication, and general expenses associated with the portion of the merchandise further manufactured in the United States, as well as a proportional amount of profit or loss attributable to the value added. Profit or loss was calculated by deducting from the sales price of the memory module all production and selling costs incurred by the company for the memory module. The total profit or loss was then allocated proportionately to all components of cost. Only the profit or loss attributable to the value added was deducted. In determining the costs incurred to produce the memory module, we included materials, fabrication, and general expenses, including selling expenses and interest expenses. No other adjustments were claimed or allowed.

Normal Value

In order to determine whether there was a sufficient volume of sales of DRAMS in the home market to serve as a viable basis for calculating NV, we compared respondents' volume of home market sales of the foreign like product to the volume of U.S. sales of the subject merchandise, in accordance with section 773(a)(1)(B) of the Act. Because the aggregate volume of home market sales of the foreign like products for all respondents was greater than five percent of the respective aggregate volume of U.S. sales for the subject merchandise, we determined that the home market provides a viable basis for calculating NV for all respondents, in accordance with section 773(a)(1)(C) of the Act.

Because LGS made some home market sales to related parties during the POR, we tested these sales to ensure that, on average, the related party sales were at ''arms-length''. To conduct this test, we compared the gross unit prices of sales to related and unrelated customers net of all movement charges, direct and indirect selling expenses, value-added tax and packing. Based on the results of that test, we discarded from LGS' home market database all sales made to a related party where that related party failed the ''arm's-length'' test.

We disregarded many of Hyundai's and LGS' sales found to have been made below the COP during the original LTFV investigation, the most recent period for which a review had been completed. Accordingly, the Department, pursuant to section 773(b) of the Act, initiated COP investigations of both respondents for purposes of this administrative review.

We calculated COP based on the sum of the costs of materials and fabrication employed in producing the foreign like product, plus selling, general, and administrative expenses (SG&A), and the cost of all expenses incidental to placing the foreign like product in condition packed ready for shipment, in accordance with section 773(b)(3) of the Act. We relied on the home market sales and COP information provided by respondents in the questionnaire responses.

In accordance with section 773(b)(1) of the Act, in order to determine whether to disregard home market sales made at prices below the COP, we examined whether, within an extended period of time, such sales were made in substantial quantities, and whether such sales were made at prices which permit the recovery of all costs within a reasonable period of time.

Pursuant to section 773(b)(2)(C)(i) of the Act, where less than 20 percent of home market sales of a given model were at prices less than the COP, we did not disregard any below-cost sales of that model because the below-cost sales were not made in ''substantial quantities.'' Where 20 percent or more of home market sales of a given model were at prices less than the COP, we found that sales of that model were

made in ''substantial quantities,''in accordance with section 773(b)(2)(B) of the Act. We then determined whether the below-cost sales of a given product are at prices which would not permit recovery of all costs within a reasonable period of time, in accordance with section 773(b)(2)(D) of the Act. If we found that sales had been made in ''substantial quantities'' and were not at prices which would permit recovery within a reasonable period of time, we disregarded the below-cost sales, in accordance with section 773(b)(1) of the Act, and based normal value on constructed value (CV).

In accordance with section 773(e) of the Act, we calculated CV based on respondents' cost of materials and fabrication employed in producing the subject merchandise, SG&A and profit incurred and realized in connection with the production and sale of the foreign like product, and U.S. packing costs. We used the costs of materials, fabrication, and G&A as reported in the CV portion of the questionnaire response. We used the U.S. packing costs as reported in the U.S. sales portion of respondents' questionnaire responses. We based selling expenses and profit on the information reported in the home market sales portion of respondents' questionnaire responses. See Certain Pasta from Italy; Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination, 61 FR 1344, 1349 (January 19, 1996). For selling expenses, we used the average of above-cost per-unit HM selling expenses weighted by the total quantity of home market sales sold. For actual profit, we first calculated the difference between the home market sales value and home market COP, and divided the difference by the home market COP. We then multiplied this percentage by the COP for each U.S. model to derive an actual profit.

For both respondents, the Department relied on the submitted COP and CV information. There were no adjustments to respondents' reported COP and CV data.

For price-to-price comparisons, we based NV on the price at which the foreign like product is first sold for consumption in the exporting country, in the usual commercial quantities and in the ordinary course of trade, and to the extent practicable, at the same level of trade, as defined by section 773(a)(1)(B)(i) of the Act. We compared the U.S. prices of individual transactions to the monthly weighted-average price of sales of the foreign like product. We calculated NV based on delivered prices to unrelated customers and, where appropriate, to related customers in the home market. In calculating NV, we made adjustments, where appropriate, for inland freight, inland insurance, discounts, rebates, and Korean brokerage and handling charges.

Both respondents only had CEP sales during the POR. For comparisons to CEP sales, we reduced NV, where appropriate, for home market credit expenses, advertising expenses, royalty expenses, and bank charges in accordance with section 773(a)(6) of the Act, due to differences in circumstances of sale. We also reduced NV by packing costs incurred in the home market, in accordance with section 773(a)(6)(B)(i) of the Act. In addition, we increased NV for U.S. packing costs, in accordance with section 773(a)(6)(A) of the Act. We also made further adjustments, when applicable, to account for differences in physical characteristics of the merchandise, in accordance with 19 CFR 353.57 of the Department's regulations.

Level of Trade and CEP Offset

As set forth in section 773(a)(2)(B)(i) of the Act and in the Statement of Administrative Action (SAA) accompanying the Uruguay Round Agreements Act, at 829–831, to the extent practicable, the Department will calculate NV based on sales at the same level of trade as the U.S. sale. When the Department is unable to find sale(s) in the comparison market at the same level of trade as the U.S. sale(s), the Department may compare sales in the U.S. and foreign markets at a different level of trade.

In accordance with section 773(a)(7)(A) of the Act, if we compare a U.S. sale at one level of trade to normal value sales at a different level of trade, the Department will adjust the NV to account for the difference in level of trade if two conditions are met. First, in order to determine that there are distinct levels of trade, there must be differences between the actual selling functions performed by the seller at the level of trade of the U.S. sale and at the level of trade of the NV sale. Second, the differences must affect price comparability as evidenced by a pattern of consistent price differences between sales at the different levels of trade in the market in which normal value is determined. When constructed export price is applicable, section 773(a)(7)(B) of the Act establishes the procedures for making a constructed export price offset when: (1) NV is at a different level of trade, and (2) the data available do not provide an appropriate basis for a level of trade adjustment. Also, in accordance with section 773(a)(7)(B), to qualify for a CEP offset, the level of trade in the home market must constitute a more advanced stage of distribution than the level of trade of the CEP sales.

In order to identify levels of trade, the Department must review information concerning selling functions of the manufacturer/exporter. We reviewed the questionnaire responses of both respondents to establish whether there were sales at different levels of trade based on selling functions performed and services offered to each customer or customer class. For both respondents, we identified one level of trade in the home market with direct sales by the parent corporation to the domestic customer. These direct sales were made by both respondents to original equipment manufacturers (OEMs) and to distributors. In addition, all sales, whether made to OEM customers or to distributors, included the same selling functions. For the U.S. market, all sales for both respondents were reported as CEP sales. The level of trade of the U.S. sales is determined for the sale to the affiliated importer rather than the resale to the unaffiliated customer. We examined the selling functions performed by the Korean companies for U.S. CEP sales and preliminarily determine that they are at a different level of trade from the Korean companies' home market sales because the Korean companies engaged in fewer selling functions for the adjusted CEP sales than for their home market sales. For instance, the Korean companies did not engage in any general promotion, marketing activities, or price negotiations for U.S. sales.

Because we compared CEP sales to home market sales at a different level of trade, we examined whether a level of trade adjustment may be appropriate. In this case, both respondents only sold at one level of trade in the home market; therefore, there is no basis upon which either respondent can demonstrate a consistent pattern of price differences between levels of trade. Further, we do not have information which would allow us to examine pricing patterns based on the respondents' sales of other products and there is no other record information on which such an analysis could be based. Because the data available do not provide an appropriate basis for making a level of trade adjustment but the level of trade in the HM is a more advanced stage of distribution than the level of trade of the CEP sales, a CEP offset is appropriate. Both respondents claimed a CEP offset. We applied the CEP offset to normal value or constructed value, as appropriate. The level of trade

methodology employed by the Department in these preliminary results of review is based on the facts particular to this review. The Department will continue to examine its policy for making level of trade comparisons and adjustments for its final results of review.

Because both respondents made sales at differing levels of trade in the home market and in the United States, and because we determined it was not possible to quantify the price differences resulting from the differing levels of trade, we made a CEP offset to NV for both respondents pursuant to section 773(a)(7)(B) of the Act. The CEP offset consisted of an amount equal to the lesser of the weighted-average U.S. indirect selling expenses and U.S. commissions or home market indirect selling expenses. No other adjustments were claimed or allowed.

Fair Value Comparisons

To determine whether sales of DRAMS by respondents to the United States were made at less than fair value, we compared the CEP to the NV, as described in the ''United States Price'' and ''Normal Value'' sections of this notice. In accordance with section 777A(d)(2), we calculated monthly weighted-average prices for NV and compared these to individual U.S. transactions.

Preliminary Results of the Review

As a result of this review, we preliminarily determine that the following weighted-average dumping margins exist for the POR:

Manufacturer/exporter	Percent margin
Hyundai Electronic Industries, Inc.	0.00
LG Semicon Co., Ltd	0.00

The Department shall determine, and Customs shall assess, antidumping duties on all appropriate entries. Individual differences between United States price and NV may vary from the percentages stated above. The Department will issue appraisement instructions directly to Customs. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the determination and for future deposits of estimated duties.

Furthermore, the following deposit requirements will be effective upon completion of the final results of these administrative reviews for all shipments of DRAMs from Korea entered, or withdrawn from warehouse, for consumption on or after publication date of the final results of these administrative reviews, as provided by section 751(a)(1) of the Act: (1) The cash deposit rates for Hyundai and LGS, because their weighted-average margins were de minimis, will be zero percent; (2) for merchandise exported by manufacturers or exporters not covered in this review but covered in the original LTFV investigation or a previous review, the cash deposit will continue to be the most recent rate published in the final determination or final results for which the manufacturer or exporter received a company-specific rate; (3) if the exporter is not a firm covered in this review, a previous review, or the original investigation, but the manufacturer is, the cash deposit rate will be that established for the manufacturer of the merchandise in the final results of the most recent review, or the LTFV investigation; and (4) if neither the exporter nor the manufacturer is a firm covered in this or any previous reviews, the cash deposit rate will be 3.85 percent, the ''all-others'' rate established in the LTFV investigation. These deposit requirements, when imposed, shall remain in effect until publication of the final results of the next administrative review.

Interested parties may request disclosure within five days of the date of publication of this notice, and may request a hearing within ten days of the date of publication. Any hearing, if requested, will be held as early as convenient for the parties but not later than 44 days after the date of publication or the first work day thereafter. Case briefs or other written comments from interested parties may be submitted not later than 30 days after the date of publication of this notice. Rebuttal briefs and rebuttal comments, limited to issues in the case briefs, may be filed not later than 37 days after the date of publication of this notice. The Department will publish the final results of this administrative review, including the results of its analysis of issues raised in any such written comments.

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 353.26(b) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This administrative review and notice are in accordance with section 751(a)(1) of the Tariff Act (19 U.S.C. 1675(a)(1)) and 19 CFR 353.22.

DATED: June 27, 1996/

Robert S. LaRussa,

Acting Assistant Secretary for Import Administration.

[FR Doc. 96–17462 Filed 7–8–96; 8:45 am]

BILLING CODE 3510–DS–P

[A–580–807]

Polyethylene Terephthalate Film from Korea: Preliminary Results of Antidumping Duty Administrative Review, Intent to Revoke the Order in Part, and Termination in Part

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Preliminary Results of Antidumping Duty Administrative Review, Intent to Revoke the Order in Part, and Termination in Part.

SUMMARY: In response to a request from two respondents and three U.S. producers, the Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on polyethylene terephthalate film, sheet, and strip (PET film) from the Republic of Korea. The review covers three manufacturers/exporters of the subject merchandise to the United States and the period June 1, 1994 through May 31, 1995. The review indicates the existence of sales below normal value for certain manufacturers/exporters during the period of review.

We preliminarily determine the dumping margin for Kolon Industries (Kolon) to be [zero or de minimis] percent during the period June 1, 1994 through May 31, 1995. Based on three years of sales at not less than normal value (NV), we intend to revoke the order with respect to Kolon if the preliminary results of this review are affirmed in our final results.

If these preliminary results are adopted in our final results of review, we will instruct the U.S. Customs Service to assess antidumping duties equal to the difference between the United States Price and NV.

On June 26, 1996, in accordance with 19 CFR 353.25, we issued a revocation of the order with respect to Cheil Synthetics Inc. (Cheil). Accordingly, we are terminating this review of Cheil.

Interested parties are invited to comment on these preliminary results. Parties who submit argument in this proceeding are requested to submit with the argument (1) a statement of the issue

and (2) a brief summary of the argument (no longer than five pages, including footnotes).

EFFECTIVE DATE: July 9, 1996.

FOR FURTHER INFORMATION CONTACT: Michael J. Heaney or John Kugelman, Office of Antidumping Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC. 20230; telephone (202) 482–4475/0649.

APPLICABLE STATUTE: Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended (the Act) are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Rounds Agreements Act (URAA). In addition, unless otherwise indicated, all citations to the Department's regulations are to the current regulations, as amended by the interim regulations published in the Federal Register on May 11, 1995 (60 FR 25130).

SUPPLEMENTARY INFORMATION:

Background

The Department published an antidumping duty order on PET film from the Republic of Korea on June 5, 1991 (56 FR 25660). The Department published a notice of ''Opportunity To Request Administrative Review'' of the antidumping duty order for the 1994/1995 review period on June 6, 1995 (60 FR 29821). On June 26, 1995, Cheil requested that the Department conduct an administrative review of the antidumping duty order on PET film from the Republic of Korea. On June 29, 1995, the petitioners, E.I. DuPont Nemours & Co., Inc., Hoescht Celanese Corporation, and ICI Americas, Inc. requested reviews of Cheil, Kolon, SKC Limited (SKC), and STC corporation (STC). SKC and Kolon filed requests for review on June 29, 1995 and June 30, 1995, respectively. We initiated the review on July 14, 1995 (60 FR 36260).

The Department extended the time limits for completion of the preliminary and final results of review. *See Antidumping Duty Administrative Reviews: Time Limits,* 61 FR 8911 (March 6, 1996).

On June xx, 1996, the Department revoked the order in part with respect to Cheil. Accordingly, we are terminating this review with respect to Cheil.

Intent to Revoke

In its submission of June 30, 1995, Kolon requested, pursuant to 19 CFR 353.25(b), revocation of the order with respect to its sales of PET film. Kolon certified in its June 30, 1995 submission that (1) it sold the subject merchandise at not less than NV during the relevant review period, and (2) that in the future it will not see the subject merchandise at less than NV. Kolon indicated in its June 30, 1995 submission that it did not believe that the agreement required under 19 CFR 353.25(a)(2)(iii) was applicable to its request because there had not been any finding that its sales were sold at less than NV.

On February 12, 1996, the Department issued an amended final results of the first review of the antidumping duty order on PET film from Korea (61 FR 5375). In this amended final, we determined that Kolon made sales at less than NV during the relevant period. Therefore, we permitted Kolon to perfect its timely request for revocation. On June 25, 1996, Kolon amended its request to include, in accordance with 19 CFR 353.25(a)(2)(iii), an agreement to immediate reinstatement in the order if any producer or reseller is subject to the order and the Department concludes that Kolon sold below NV under section 353.22(f) subsequent to revocation. Based on the final results of the two preceding reviews and the preliminary results of this review, Kolon has demonstrated three consecutive years of sales at not less than NV.

If the final results of this review demonstrate that Kolon sold the merchandise at not less than NV, and if the Department determines that it is not likely that Kolon will sell the subject merchandise at less than NV in the future, we intend to revoke the order with respect to merchandise produced and exported by Kolon.

Scope of the Review

Imports covered by this review are shipments of all gauges of raw, pretreated, or primed polyethylene terephthalate film, sheet, and strip, whether extruded or coextruded. The films excluded from this review are metallized films and other finished films that have had at least one of their surfaces modified by the application of a performance-enhancing resinous or inorganic layer of more than 0.00001 inches (0.254 micrometers) thick. Roller transport cleaning film which has at least one of its surfaces modified by the application of 0.5 micrometers of SBR latex has also been ruled as not within the scope of the order.

PET film is currently classifiable under Harmonized Tariff Schedule (HTS) subheading 3920.62.00.00. The HTS subheading is provided for convenience and for U.S. Customs purposes. The written description remains dispositive as to the scope of the product coverage.

The review covers the period June 1, 1994 through May 31, 1995. The Department is conducting this review in accordance with section 751 of the Act, as amended.

Verification

As provided in section 782(i) of the Act, we verified information provided by Kolon using standard verification procedures, including onsite inspection of the manufacturer's facilities, the examination of relevant sales and financial records, and selection of original documentation containing relevant information. Our verification results are outlined in the public version of the Kolon verification report.

United States Price (USP)

In calculating USP, the Department treated respondents' sales as export price (EP) sales, as defined in section 772(a) of the Act, when the merchandise was sold to unaffiliated U.S. purchasers prior to the date of importation. The Department treated respondents' sales as constructed export price (CEP) sales, as defined in section 772(b) of the Act, when the merchandise was sold to unrelated U.S. purchasers after importation.

EP was based on the ex-factory, f.o.b. Korean port, f.o.b. customer's specific delivery point, c.i.f. U.S. port, or delivered, packed prices to unrelated purchasers in the United States. We made adjustments, where applicable, for Korean and U.S. brokerage charges, terminal handling charges, truck loading charges, containerization charges, Korean and U.S. inland freight, ocean freight, wharfage expenses, U.S. duties, and rebated in accordance with section 772(c) of the Act.

CEP was based on ex-warehouse, f.o.b. customer's specific delivery point, or delivered, packed prices to unrelated purchasers in the United States. We made adjustments, where applicable, for Korean and U.S. brokerage charges, terminal handling charges, containerization charges, Korean and U.S. inland freight, ocean freight, rebates, wharfage expenses, and U.S. duties, in accordance with section 772(c) of the Act. In accordance with section 772(d)(1) of the Act, we made deductions for selling expenses associated with economic activities in the United States, including warranties, credit, commissions, postage expenses, bank charges and indirect selling expenses. Pursuant to section 772(d)(3) of the Act, the price was further reduced by an amount for profit to arrive at the CEP.

For SKC, we made an offset to interest expense for interest revenue, and for post-sale cost and quantity adjustments that were not reflected in the gross price. With respect to subject merchandise to which value was added in the United States by SKC prior to sale to unrelated customers, we deducted any increased value in accordance with section 772(d)(2) of the Act.

Normal Value

In order to determine whether there were sufficient sales of PET film in the home market (HM) to serve as a viable basis for calculating NV, we compared the volume of home market sales of PET film to the volume of PET film sold in the United States, in accordance with section 773(a)(1)(B) of the Act. Each respondent's aggregate volume of HM sales of the foreign like product was greater than five percent of its respective aggregate volume of U.S. sales of the subject merchandise. Therefore, we have based NV on HM sales.

Based on the fact that the Department had disregarded sales in the first administrative review because they were made below the cost of production (COP), the Department initiated a sales-below-cost of production (COP) investigation for each of the respondents in accordance with section 773(b) of the Act. (The first administrative review was the most recently completed review at the time that we issued our antidumping questionnaire.)

We performed a model-specific COP test in which we examined whether each HM sale was priced below the merchandise's COP. We calculated the COP of the merchandise using Kolon's, SKC's, and STC's cost of materials and fabrication for the foreign like product, plus amounts for home market general expenses and packing costs in accordance with section 773(b)(3) of the Act.

In accordance with section 773(b)(1) of the Act, in determining whether to disregard home market sales made at prices below COP, we examined whether such sales were made within an extended period of time in substantial quantities, and whether such sales were made at prices which would permit recovery of all costs within a reasonable period of time.

Pursuant to section 773(b)(2)(C) of the Act, where less than 20 percent of a respondent's sales of a given model were at prices less than COP, we did not disregard any below-cost sales of that model because these below-cost sales were not made in substantial quantities. We found that, for certain models of PET film, 20 percent or more of the home market sales were sold at below-cost prices. Where 20 percent or more of a respondent's home market sales of a given model were at prices less than the COP, we disregarded the below-cost sales because such sales were found to be made (1) in substantial quantities within the POR (*i.e.,* within an extended period of time) and (2) at prices which would not permit recovery of all costs within a reasonable period of time, in accordance with section 773(b)(2)(D) of the Act (*i.e.,* the sales were made at prices below the weighted-average per unit COP for the POR). We used the remaining above-cost sales as the basis of determining NV if such sales existed, in accordance with section 773(b)(1). For those models of the subject merchandise for which there were no above-cost sales available for matching purposes, we compared U.S. price to constructed value (CV).

In accordance with section 773(e)(1) of the Act, we calculated CV based on the sum of the respondent's cost of materials, fabrication, and general expenses. In accordance with section 773(e)(2)(A) of the Act, we based selling, general, and administrative (SG&A) expenses and profit on the amounts incurred and realized by the respondents in connection with the production and sale of the foreign like product in the ordinary course of trade for consumption in the foreign country. For selling expenses we used the weighted-average HM selling expenses. Pursuant to section 773(e)(3) of the Act, we included U.S. packing.

In accordance with section 773(a)(6), we adjusted NV, where appropriate, by deducting home market packing expenses and adding U.S. Packing expenses. We also adjusted NV to reflect deductions for HM inland freight, loading charges, and credit expenses. For comparisons to EP, we made an addition to NV for differences in warranty and credit expenses as circumstance-of-sale adjustments pursuant to section 773(a)(6)(C) of the Act.

Level of Trade and CEP Offset

As set forth in section 773(a)(1)(B)(i) of the Act and in the Statement of Administrative Action (SAA) accompanying the URAA, *reprinted in* H.R. Doc. No. 316, 103d Cong., 2d Session 829–831 (1994), to the extent practicable, the Department will calculate NV based on sales at the same level of trade as the U.S. sale. When the Department is unable to find sale(s) in the comparison market at the same level of trade as the U.S. sale(s), the Department may compare sales in the U.S. and foreign markets at a different level of trade.

In accordance with section 773(a)(7)(A) of the Act, if we compare a U.S. sale at one level of trade to NV sales at a different level of trade, the Department will adjust the NV to account for differences in level of trade if two conditions are met. First there must be differences between the actual selling functions performed by the seller at the level of trade of the U.S. sale and at the level of trade of the comparison market sale used to determine NV. Second, the differences must affect price comparability as evidenced by a pattern of consistent price differences between sales at the different levels of trade in the market in which NV is determined. When CEP is applicable, section 773(a)(7)(B) of the Act establishes the procedures for making a CEP ''offset'' when two conditions exist: (1) NV is established at a level of trade which constitutes a more advanced stage of distribution than the level of trade of the CEP; and (2) the data available do not provide an appropriate basis for a level-of-trade adjustment.

In order to implement these principles, each of the respondents provided information with respect to its selling activities associated with each channel of distribution. All of the respondents identified two channels of distribution in the home market: (1) wholesalers/distributors and (2) end-users. For both channels, all of the respondents perform similar selling functions such as market research and after sales warranty services. Because channels of distribution do not qualify as separate levels of trade when the selling functions performed for each customer class are sufficiently similar, we determined that there exists one level of trade for each of the respondents' home market sales.

Each of the respondents made CEP and EP sales to the United States market and claimed either a level of trade adjustment for its CEP sales, or a CEP offset. The level of trade of the U.S. sale is determined by the adjusted price of the CEP sale. Based on each of the respondents' questionnaire responses to our requests for supplemental information, we determined a difference between the actual selling functions performed by respondents at the level of trade of the CEP sale and the level of trade of the HM sale. The adjusted CEP sales do not reflect the selling functions performed for end-users or distributors in the Korean market.

Kolon provides inventory maintenance, after-sales and warranty services, and advertising on behalf of its customer for HM sales. Kolon does not provide these services on its CEP sales. SKC provides market research,

engineering services, inventory maintenance, and delivery services on its HM sales. SKC does not provide these services on its CEP sales. STC provides inventory maintenance, after sales-services and warranty assistance, entertainment of customers, and marketing research on its HM sales. STC does not provide these services on its CEP sales. Therefore, the selling functions performed by each of the respondents for CEP sales are sufficiently different than for HM sales so as to establish different levels of trade.

Because we compared these CEP sales to HM sales at a different level of trade, we examined whether a level-of-trade adjustment may be appropriate. In this case each of the respondents only sold at one level of trade in the home market; therefore, there is no basis upon which any of the respondents has demonstrated a consistent pattern of price differences between levels of trade. Further, we do not have the information which would allow us to examine pricing patterns of respondents' sales of other similar products, and there is no other respondent's or other information on the record to analyze whether the adjustment is appropriate.

Because the data available do not provide an appropriate basis for making a level-of-trade adjustment but the level of trade in Korea for each respondent is at a more advanced stage than the level of trade of the CEP sales, a CEP offset is appropriate in accordance with section 773(a)(7)(B) of the Act. Each respondent claimed a CEP offset, which we applied to NV. We based the CEP offset amount on the amount of home market indirect selling expenses, and limited the deduction for HM indirect selling expenses to the amount of indirect selling expenses incurred on sales in the United States, in accordance with section 772(d)(1)(D) of the Act. The level-of-trade methodology used in this review is based on the facts particular to this review. The Department will continue to examine its policy for making level-of-trade comparisons and adjustments for the final results of this review.

Fair Value Comparisons

To determine whether sales of PET film in the United States were made at less than fair value, we compared USP to the NV, as described in the ''United States Price'' and ''Normal Value'' sections of this notice. In accordance with section 777(A) of the Act, we calculated monthly weighted-average prices for NV and compared these to individual U.S. transactions.

Preliminary Results of Review

We preliminarily determine that the following margins exist for the period June 1, 1994 through May 31, 1995:

Manufacturer/exporter	Margin
Kolon	0.14
SKC	1.91
STC	4.98

Parties to this proceeding may request disclosure within five days of publication of this notice and any interested party may request a hearing within 10 days of publication. Any hearing, if requested, will be held 44 days after the date of publication, or the first working day thereafter. Interested parties may submit case briefs and/or written comments no later than 30 days after the date of publication. Rebuttal briefs and rebuttals to written comments, limited to issues raised in such briefs or comments, may be filed no later than 37 days after the date of publication. The Department will publish the final results of this administrative review, which will include the results of its analysis of issues raised in any such written comments or at a hearing.

The Department shall determine, and Customs shall assess, antidumping duties on all appropriate entries. Individual differences between USP and NV may vary from the percentages stated above. The Department will issue appraisement instructions directly to Customs. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the determination and for future deposits of estimated duties.

Furthermore, the following deposit requirements will be effective upon completion of the final results of these administrative reviews for all shipments of PET film from the Republic of Korea entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of these administrative reviews, as provided by section 751(a)(1) of the Act: (1) The cash deposit rate for reviewed firms will be the rate established in the final results of administrative review; (2) for merchandise exported by manufacturers or exporters not covered in these reviews but covered in the original less-than-fair value (LTFV) investigation or a previous review, the cash deposit will continue to be the most recent rate published in the final determination or final results for which the manufacturer or exporter received a company-specific rate; (3) if the exporter is not a firm covered in these reviews, or the original investigation, but the manufacturer is, the cash deposit rate will be that established for the manufacturer of the merchandise in the final results of these reviews, or the LTFV investigation; and (4) if neither the exporter nor the manufacturer is a firm covered in these or any previous reviews, the cash deposit rate will be 4.82%, the ''all others'' rate established in the LTFV investigation.

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 353.26(b) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during these review periods. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This administrative review and notice are in accordance with Section 751(a)(1) of the Act (19 U.S.C. 1675(a)(1).

Dated: July 1, 1996.

Robert S. LaRussa,

Acting Assistant Secretary for Import Administration.

[FR Doc. 96–17464 Filed 7–8–96; 8:45 am]

BILLING CODE 3510–DS–M

National Oceanic and Atmospheric Administration

[I.D. 070296B]

Gulf of Mexico Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) will convene a public meeting of the Red Drum Stock Assessment Panel (Panel).

DATES: This meeting will begin at 1:00 p.m. on July 29, 1996, and will conclude at 5:00 p.m. on July 31, 1996.

ADDRESSES: The meeting will be held at the National Marine Fisheries Service Southeast Fisheries Science Center, 75 Virginia Beach Drive, Miami, FL.

FOR FURTHER INFORMATION CONTACT: Wayne Swingle, Executive Director, 5401 West Kennedy Boulevard, Suite 331, Tampa, FL 33609; telephone: (813) 228–2815.

SUPPLEMENTARY INFORMATION: The Panel will review stock assessment information prepared by NMFS for the Gulf stock and will assess whether the

stock has been restored to a level above the overfishing threshold. If the stock has been restored, the Panel will develop an estimate of the range of acceptable biological catch (ABC) for the stock. The Council will review the Panel's report at its September meeting and may specify a total allowable catch (TAC) within the range of ABC for the fishery. Implementation of a TAC will, however, require an amendment to the fishery management plan for red drum. The amendment action would require approximately 9 months for implementation.

The red drum stock was classified as overfished in 1986 and harvest and possession of red drum in Federal waters was prohibited in 1987. Most actions to restore the stock have been taken by the individual Gulf states.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Anne Alford at the Council (see **ADDRESSES**) by July 22, 1996.

Dated: July 2, 1996.

Richard W. Surdi,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 96–17439 Filed 7–8–96; 8:45 am]

BILLING CODE 3510–22–F

[I.D. 070296A]

Mid-Atlantic Fishery Management Council; Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's Bluefish Advisory Panel (together with the Atlantic States Marine Fisheries Commission's Bluefish Advisory Panel) will hold a public meeting.

DATES: The meeting will be held on July 24, 1996, from 1:30 p.m. until 5:30 p.m.

ADDRESSES: The meeting will be held at the Holiday Inn at the Crossings, 801 Greenwich Avenue, Warwick, RI; telephone: (401) 732–6000.

Council address: Mid-Atlantic Fishery Management Council, 300 S. New Street, Dover, DE 19901; telephone: (302) 674–2331.

FOR FURTHER INFORMATION CONTACT: David R. Keifer, Executive Director; telephone: (302) 674–2331.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is for discussion of technical/assessment report, Amendment #1 overfishing definition, and Amendment #1 management measures.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Joanna Davis at the Council (see **ADDRESSES**) at least 5 days prior to the meeting date.

Dated: July 2, 1996.

Richard W. Surdi,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 96–17438 Filed 7–8–96; 8:45 am]

BILLING CODE 3510–22–F

[Docket No. 960111003–6068–03; I.D. 070296C]

Pacific Halibut Fisheries; 1996 Halibut Landing Report No. 4

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Inseason action.

SUMMARY: The Assistant Administrator for Fisheries, NOAA, on behalf of the International Pacific Halibut Commission (IPHC), publishes these inseason actions pursuant to IPHC regulations approved by the U.S. Government to govern the Pacific halibut fishery. These actions are intended to enhance the conservation of the Pacific halibut stock.

FOR FURTHER INFORMATION CONTACT: Steven Pennoyer, 907–586–7221; William W. Stelle, Jr., 206–526–6140; or Donald McCaughran, 206–634–1838.

SUPPLEMENTARY INFORMATION: The IPHC, under the Convention between the United States of America and Canada for the Preservation of the Halibut Fishery of the Northern Pacific Ocean and Bering Sea (signed at Ottawa, Ontario, on March 2, 1953), as amended by a Protocol Amending the Convention (signed at Washington, DC, on March 29, 1979), has issued this inseason action pursuant to IPHC regulations governing the Pacific halibut fishery. The regulations have been approved by NMFS (60 FR 14651, March 20, 1995, and amended at 61 FR 11337, March 20, 1996). On behalf of the IPHC, this inseason action is published in the Federal Register to provide additional notice of its effectiveness, and to inform persons subject to the inseason action of the restrictions and requirements established therein.

Inseason Action

1996 Halibut Landing Report No. 4

Area 2B Commercial Fishery Update

Halibut landings from Area 2B total 4.45 million pounds (2,018.50 metric tons (mt)) through June 17, leaving 5.07 million pounds (2,299.73 mt) of the catch limit to be caught. The fishery will continue until all Individual Vessel Quotas (IFQ) have been filled, or November 15, whichever is earlier. Annette Island Reserve Fishery in Area 2C.

The Metlakatla Indian community has been authorized by the U.S. Government to conduct a commercial halibut fishery within the Annette Island Reserve. Four 48-hour fishing periods occurred between April 27 and June 10, producing a total catch of 21,400 pounds (9.70 mt).

Alaskan Commercial Fishery Update

It is estimated that the following catches and number of landings were made in the Alaskan IFQ and Community Development Quota (CDQ) fisheries through June 12, 1996.

Area	Catch limit (000's pounds)	Catch (000's pounds)	Number of landings
2C	9,000	4,803	1,334
3A	20,000	8,196	1,139
3B	3,700	806	131
4A	1,950	268	40
4B	2,310	314	16
4C	770	1	2
4D	770	157	7
4E	20	34	45
Total	38,620	14,579	2,714

During the same time period in 1995, March 15 through June 9, 8.0 million pounds (3,628.77 mt) were landed in the Alaskan IFQ and CDQ fisheries.

Dated: July 2, 1996.

Richard W. Surdi,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 96–17437 Filed 7–8–96; 8:45 am]

BILLING CODE 3510–22–P

[I.D. 070196F]

Marine Mammals; Scientific Research Permits (P607 and P614)

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Receipt of applications.

SUMMARY: Notice is hereby given that Cynthia K. Riseling, 12659 16th Street, Chino, CA 91710 (P607), and Dr. David R. Young, Oregon State University College of Oceanography, Hatfield Marine Science Center, Newport, OR 97365–5260 (P614), have applied in due form for a permit to take marine mammals for purposes of scientific research.

DATES: Written comments must be received on or before August 8, 1996.

ADDRESSES: The applications and related documents are available for review upon written request or by appointment in the following office(s):

(P607 and 614): Permits Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13130, Silver Spring, MD 20910 (301/713–2289);

(P607 and 614): Director, Southwest Region, NMFS, 501 West Ocean Blvd., Long Beach, CA 90802–4213 (310/980–4001); and

(P614): Director, Northwest Region, NMFS, 7600 Sand Point Way, NE, BIN C15700, Bldg., 1, Seattle, WA 98115–0070.

Written data or views, or requests for a public hearing on these requests, should be submitted to the Director, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13130, Silver Spring, MD 20910. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular request would be appropriate.

Concurrent with the publication of this notice in the Federal Register, NMFS is forwarding copies of this application to the Marine Mammal Commission and its Committee of Scientific Advisors.

SUPPLEMENTARY INFORMATION: The subject permits are requested 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).

Cynthia Riseling (P607) requests authority to sample up to 35 juvenile California sea lions (*Zalophus californianus*) annually for three years. Animals sampled will be from stranded rehabilitated stocks at marine mammal stranding centers in California. Three cultures will be taken from the skin, throat, and vaginal/urethral area to study the normal bacteria flora of this animal. If fecal samples are available, they will be collected. The question the applicant seeks to answer is are normal bacterial flora of these animals causing disease in humans?

David R. Young (P614) requests authority to import from Russia blubber, liver, muscle and composited seal blubber oil taken from Baikal seals (*Phoca sibirica*). Samples will be taken from eight carcasses which were either beached, stranded, or hunted under Russia's legal culling system from areas of Lake Baikal. The researchers seek to establish the level of toxic contaminants [PCBs; DDTs; PAHs; Organic Mercury; Trace Metals] in indicator tissues of the Baikal seal, and also components of the animal's food web.

Date: July 1, 1996.

Ann Hochman,

Acting Chief, Permits and Documentation Division, Office of Protected Resources, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 96–17362 Filed 7–8–96; 8:45 am]

BILLING CODE 3510–22–F

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Limits for Certain Cotton and Man-Made Fiber Textile Products Produced or Manufactured in Turkey

July 2, 1996.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs adjusting limits.

EFFECTIVE DATE: July 3, 1996.

FOR FURTHER INFORMATION CONTACT: Naomi Freeman, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927–5850. For information on embargoes and quota re-openings, call (202) 482–3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Uruguay Round Agreements Act.

The current limit for Category 611 is being increased for swing and carryover, reducing the Fabric Group limit to account for the swing being applied.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see Federal Register notice 60 FR 65299, published on December 19, 1995). Also see 60 FR 57576, published on November 16, 1995.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles and Clothing, but are designed to assist only in the implementation of certain of their provisions.

Troy H. Cribb,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

July 2, 1996.

Commissioner of Customs,

Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on November 9, 1995, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool and man-made fiber textile products, produced or manufactured in Turkey and exported during the twelve-month period which began on January 1, 1996 and extends through December 31, 1996.

Effective on July 3, 1996, you are directed to adjust the limits for the following categories, as provided for in the Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles and Clothing:

Category	Adjusted twelve-month limit [1]
Fabric Group 219, 313, 314, 315, 317, 326, 617, 625/626/627/628/629, as a group.	148,042,490 square meters.
Limit not in a group 611	53,998,884 square meters.

[1] The limits have not been adjusted to account for any imports exported after December 31, 1995.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Troy H. Cribb,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 96–17453 Filed 7–8–96; 8:45 am]

BILLING CODE 3510–DR–F

DEPARTMENT OF DEFENSE

Office of the Secretary

Public Information Collection Requirement Submitted to the Office of Management and Budget (OMB) for Review; Notice

The Department of Defense has submitted to OMB for a clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Title and OMB Control Number: Acquisition Management Systems and Data Requirements Control List (AMSDL); OMB Number 0704–0188.

Type of Request: Revision.

Number of Respondents: 1,300.

Responses per Respondent: 540.

Annual Responses: 702,000.

Average Burden per Response: 110 hours.

Annual Burden Hours: 77,220,000.

Needs and Uses: The AMSDL is a list of data requirements used in Department of Defense contracts. The information collected hereby, is used to support the design, test, manufacture, training, operation and maintenance of procured items.

Affected Public: Business or other for profit; Not-for-profit institutions.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Mr. Peter N. Weiss.

Written comments and recommendations on the proposed information collection should be sent to Mr. Weiss at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Mr. William Pearce.

Written requests for copies of the information collection proposal should be sent to Mr. Pearce, WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202–4302.

Dated: July 2, 1996.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 96–17338 Filed 7–8–96; 8:45 am]

BILLING CODE 5000–04–M

Department of the Army

Availability of Non-Exclusive, Exclusive, or Partially-Exclusive Licensing Ferroelectric Materials Technology

AGENCY: U.S. Army Research Laboratory, Maryland.

ACTION: Notice.

SUMMARY: The Department of the Army announces the general availability of exclusive, partially exclusive or non-exclusive Licenses under patents U.S. Patent No. 5,486,491, issued 23 Jan 1996, entitled ''Ceramic Ferroelectric Composite Material—BSTO–ZR02''; U.S. Patent No. 5,312,790, issued 17 May 1994, entitled ''Ceramic Ferroelectric Material''; and U.S. Patent No. 5,427,998, issued 27 Jun 1995, entitled ''Ceramic Ferroelectric Composite Material—BSTO–MGO'' Licenses shall comply with 35 U.S.C. 209 and 37 CFR 404.

FOR FURTHER INFORMATION CONTACT: Mr. Michael D. Rausa, Technology Transfer Office (APG Site), AMSRL–TT–TA, U.S. Army Research Laboratory, Aberdeen Proving Ground, MD 21005–5425, telephone number (410) 278–5028.

SUPPLEMENTARY INFORMATION: Written objections must be filed within 3 months from the date of publication of this notice in the Federal Register.

Gregory D. Showalter,

Army Federal Register Liaison Officer.

[FR Doc. 96–17415 Filed 7–8–96; 8:45 am]

BILLING CODE 3710–08–M

Availability of Non-Exclusive, Exclusive, or Partially-Exclusive Licensing Composite Materials Manufacturing Technology

AGENCY: U.S. Army Research Laboratory, Maryland.

ACTION: Notice.

SUMMARY: The Department of the Army announces the general availability of exclusive, partially exclusive or non-exclusive Licenses under patent 5,210,499, issued 11 May 1993, entitled ''In-Situ Sensor Method and Device''. Licenses shall comply with 35 U.S.C. 209 and 37 CFR 404.

FOR FURTHER INFORMATION CONTACT: Mr. Michael D. Rausa, Technology Transfer Office (APG Site), AMSRL–TT–TA, U.S. Army Research Laboratory, Aberdeen Proving Ground, MD 21005–5425, telephone number (410) 278–5028.

SUPPLEMENTARY INFORMATION: Written objections must be filed within 3 months from the date of publication of this notice in the Federal Register.

Gregory D. Showalter,

Army Federal Register Liaison Officer.

[FR Doc. 96–17414 Filed 7–8–96; 8:45 am]

BILLING CODE 3710–08–M

Availability of Exclusive, Partially Exclusive, or Nonexclusive Licenses

AGENCY: U.S. Army Soldier Systems Command.

ACTION: Notice.

SUMMARY: The Department of the Army 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 404.

Issued Patent: 5,521,094.

Title: Method for Establishing Lethality of High Temperature Food Processing.

Issue Date: 5/28/96.

Issued Patent: 5,517,981.

Title: Water-Activated Chemical Heater with Suppressed Hydrogen.

Issue Date: 5/21/96.

Issued Patent: 5,458,896.

Title: Technique for Determining the Oxidative Status of Packaged Dry or Intermediate Moisture Foods.

Issue Date: 10/17/95.

Issued Patent: 5,438,192.

Title: Photodynamic Protein-Based Photodetector and Photodetector System for Image Detection and Processing.

Issue Date: 08/01/95.

Issued Patent: 5,402,362.

Title: Method to Utilize Trail Dyeings to Improve Color Formulations.

Issue Date: 03/28/95.

FOR FURTHER INFORMATION CONTACT: For further information or a copy of one of the listed patents, please contact either Mr. Vincent Ranucci, Patent Counsel at 508–233–4510 or Ms. Jessica M. Niro, Paralegal Specialist at 508–233–4513 or by fax at 508–233–5167 or by writing to the U.S. Army Soldier Systems Command, Office of Chief Counsel, ATTN: Patents, Natrick, MA 01760–5035.

SUPPLEMENTARY INFORMATION: None.

Gregory D. Showalter,

Army Federal Register Liaison Officer.

[FR Doc. 96–17413 Filed 7–8–96; 8:45 am]

BILLING CODE 3710–08–M

Corps of Engineers

Intent to Prepare a Draft Environmental Impact Statement (DEIS) for the Baltimore Metropolitan Water Resources Study-Gwynns Falls in Baltimore County, Maryland

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

ACTION: Notice of Intent.

SUMMARY: In accordance with the National Environmental Policy Act (NEPA), the Baltimore District, U.S. Army Corps of Engineers is initiating the Baltimore Metropolitan Water Resources Feasibility Study for the Gwynns Falls sub-basin of the Patapsco River watershed. The riparian and aquatic environmental integrity of the Gwynns Falls sub-basin has been severely degraded by urbanization, inadequate infrastructure and industrial encroachment. Potential environmental restoration of streambanks, wetlands and forest buffers could restore and/or create up to 150 acres of riparian and aquatic habitat, in addition to improving water quality, low base flows, stream channel erosion, and sedimentation. A DEIS will be integrated into the feasibility study to document existing conditions, projects actions, and project effects and products. Baltimore County, Baltimore City and the State of Maryland's Department of the Environment (MDE) are the non-Federal sponsors for the project.

FOR FURTHER INFORMATION CONTACT: Questions about the proposed action and DEIS can be addressed to Mr. Richard Starr, Study Manager, Baltimore District, U.S. Army Corps of Engineers, ATTN: CENAB–PL–RP, P.O. Box 1715, Baltimore, Maryland 21203–1715, telephone (410) 962–4633. E-mail address: richard.r.starr@ccmail.nab.usace.army.mil

SUPPLEMENTARY INFORMATION: 1. The U.S. House of Representatives, Committee on Public Works and Transportation, authorized the Baltimore Metropolitan Water Resources Study-Gwynns Falls in a resolution adopted April 30, 1992.

2. The study area is located in northern Maryland. The area proposed for environmental restoration is known as the Gwynns Falls watershed and is located in highly developed portions of Baltimore County and Baltimore City. The most significant problem in the Gwynns Falls watershed is the instability of the steam channels and the loss of aquatic habitat. Due to the extensive urbanization along the narrow corridor between the Chesapeake Bay and the Fall Line within a short period of time, environmental resources and aquatic habitats have become degraded. This excessive degradation includes: flashy stormwater flows that cause streambank erosion and sedimentation, residential and industrial encroachment has limited riparian habitat and wetlands, and polluted runoff has contributed to poor water quality. These factors negatively impact the aquatic environment in the present and the future.

3. An ecosystem framework has been developed to restore the habitat and environmental integrity of Gwynns Falls. It allows potential restoration projects to be identified, evaluated, and selected on a watershed basis. Study goals and characterizations will be made of the broad Gwynns Falls watershed. Sub-basins, or hydrologic unit areas (HUAs), will then be identified, delineated and prioritized within the broad watershed. Based on the study objectives, high priority HUAs will be further characterized and problem statements for these areas will be developed. Upon the identification and characterization of the high priority HUAs, specific problem areas within them will be identified and prioritized. Preliminary conceptual restoration measures which could address the problem areas within Gwynns Falls, developing ecosystem based alternative plans for the high priority HUAs, and incrementally analyzing each alternative will follow. The final evaluation will focus on which combination of problem area restoration solutions provide the most environmental benefits, at the least cost, for a HUA ecosystem.

4. This proposed HUA restoration plan would potentially include stormwater detention measures, such as the restoration of floodplains, creation of wetlands, and conversion of existing stormwater facilities. Habitat structures would also be installed to restore aquatic habitat and provide added cover for spawning. Stream restoration would include stabilization techniques, such as rootwads, plantings and geotubes. Where feasible, fish blockages would be removed to allow for residential and migratory passage. In the Middle Branch tidal area, alternatives to create islands and restore a vegetative wetland buffer around the Harbor area will be investigated.

5. The decision to implement these actions will be based on an evaluation of the probable impact of the proposed activities on the public interest. That decision will reflect the national concern for both protection and utilization of important resources. The benefit which reasonably may be expected to accrue from the proposal will be balanced against its reasonably foreseeable detriments. The Baltimore District is preparing a DEIS which will describe the impacts of the proposed projects on environmental and cultural resources in the study area and the overall public interest. The DEIS will be in accordance with NEPA and will document all factors which may be relevant to the proposal, including the cumulative effects thereof. Among these factors are conservation, economics, aesthetics, general environmental concerns, wetlands, cultural values, fish and wildlife values, flood hazards, floodplain values, land use, recreation, water supply and conservation, water quality, energy needs, safety, and the general needs and welfare of the people. If applicable, the DEIS will also apply guidelines issued by the Environmental Protection Agency, under the authority of Section 404(b)(1) of the Clean Water Act of 1977 (Pub. L. 95–217).

6. The public involvement program will include workshops, meetings, and other coordination with interested private individuals and organizations, as well as with concerned Federal, state and local agencies. Coordination letters and newsletters have been sent to appropriate agencies, organizations, and individuals on an extensive mailing list. Additional public information will be provided through print media, mailings, radio and television announcements.

7. In addition to the Corps, the Maryland Department of the Environment, Baltimore County and Baltimore City, other participants that will be involved in the study and DEIS process include, but are not limited to the following: U.S. Environmental Protection Agency; U.S. Fish and Wildlife Service; U.S. Forest Service; U.S. Geological Survey; Natural Resource Conservation Service; and the U.S. National Park Service. The Baltimore District invites potentially affected Federal, state, and local agencies, and other organizations and entities to participate in this study.

8. The DEIS is tentatively scheduled to be available for public review in July 1998.

Harold L. Nelson,

Assistant Chief, Planning Division.

[FR Doc. 96–17411 Filed 7–8–96; 8:45 am]

BILLING CODE 3710–41–M

Intent To Prepare a Draft Environmental Impact Statement (EIS) For Howard Hanson Dam Additional Water Storage Project Feasibility Study

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

ACTION: Notice of Intent.

SUMMARY: Seattle District, US Army Corps of Engineers is proposing an Environmental Impact Statement (EIS) for a study of alternatives for restoration of anadromous fisheries and wildlife habitat and for municipal water supply

at the Howard Hanson Dam on the Green River, King County, Washington.

FOR FURTHER INFORMATION CONTACT: Questions about the proposed action and DEIS can be answered by: Mike McNeely, Seattle District, U.S. Army Corps of Engineers, Planning Branch, PO Box 3755, Seattle, Washington 98124–2255, Telephone (206) 764–3624; fax (206) 764–4470.

SUPPLEMENTARY INFORMATION:

1. Proposed Action

Howard A Hanson Dam was originally authorized as the Eagle Gorge Dam and Reservoir by the Flood Control Act of 1950. Construction was completed in 1962. It is an earthfill and rockfill structure which provides winter flood control and summer low flow augmentation. The dam is located at river mile 64.5 on the Green River, King County, Washington, 35 miles southeast of Seattle, and 35 miles northeast of Tacoma. The dam and reservoir provide approximately 106,000 acre feet of winter flood control storage reservoir and 26,000 acre feet of summer conservation storage (seasonally from March through September). This 26,000 acre feet of conservation storage provides a minimum instream flow of 110 cubic feet per second (cfs) at 98 percent reliability. The Additional Water Storage Project Feasibility Study purposes are water supply and environmental restoration. Potential benefits are: municipal and industrial (M&I) water supply and downstream low flow augmentation through added storage; and higher fish and wildlife survival through improved downstream fish passage at the dam and improved habitat.

2. Alternatives

The Corps of Engineers is currently examining four alternatives.

a. No action.

b. Water supply only via pool raise to elevation 1169.

c. Water supply/restoration via pool raise to elevation 1177.

d. Adaptive management water supply/restoration via phased pool raise to maximum elevation 1177.

3. Scoping and Public Involvement

Public involvement will be sought during the scoping process and throughout the course of the project in accordance with NEPA procedures. A public scoping process has been begun to clarify issues of major concern, identify any information sources that might be available to analyze and evaluate impact, and obtain public input on the range and acceptability of alternatives. This Notice of Intent formally commences the scoping process under NEPA. As part of the scoping process, all affected Federal, state and local agencies, Indian Tribes, general public and other interested private organizations, including environmental interest groups, are invited to comment on the scope of the EIS. Comments are requested concerning project alternatives, mitigation measures, probable significant environmental impacts, and permits or other approvals that may be required.

The following key areas have been identified to be analyzed in depth in the draft EIS:

(1) Geology and Engineering Design.
(2) Water Management.
(3) Water Quality.
(4) Fisheries.
(5) Wildlife.
(6) Wetlands.
(7) Cultural Resources.
(8) Socioeconomic Resources.

A scoping meeting has been scheduled for: July 18, 1996, in Auburn City Hall Council Chambers, 25 West Main Street, Auburn, Washington at 6 p.m.

4. Schedule

The draft EIS is scheduled for release on April 1, 1997.

Donald T. Wynn,

Colonel, Corps of Engineers, District Engineer.

[FR Doc. 96–17412 Filed 7–8–96; 8:45 am]

BILLING CODE 3710–ER–M

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Proposed collection; comment request.

SUMMARY: The Director, Information Resources Group, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before September 9, 1996.

ADDRESSES: Written comments and requests for copies of the proposed information collection requests should be addressed to Patrick J. Sherrill, Department of Education, 600 Independence Avenue, S.W., Room 5624, Regional Office Building 3, Washington, DC 20202–4651.

FOR FURTHER INFORMATION CONTACT: Patrick J. Sherrill (202) 708–8196. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Director of the Information Resources Group publishes this notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment at the address specified above. Copies of the requests are available from Patrick J. Sherrill at the address specified above.

The Department of Education is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department, (2) will this information be processed and used in a timely manner, (3) is the estimate of burden accurate, (4) how might the Department enhance the quality, utility, and clarity of the information to be collected, and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: July 2, 1996.

Gloria Parker,

Director, Information Resources Group.

Office of Postsecondary Education

Type of Review: Revision.

Title: Training Assessment Form—Title IV Student Financial Assistance Programs.

Frequency: One Time.

Affected Public: Business or other for-profit; Not-for-profit institutions.

Annual Reporting and Recordkeeping Hour Burden: Responses: 25,000; Burden Hours: 2,000.

Abstract: The information collected will aid in the monitoring of contractors and non-Federal trainers. It will also measure the effectiveness of training offered to financial aid administrators, counselors, fiscal officers, and other administrators participating in student financial aid and other Federal programs.

[FR Doc. 96–17357 Filed 7–8–96; 8:45 am]
BILLING CODE 4000–01–P

Recognition of Accrediting Agencies, State Agencies for Approval of Public Postsecondary Vocational Education, and State Agencies for Approval of Nurse Education

AGENCY: Department of Education.

ACTION: Request for Comments on Agencies applying to the Secretary for Initial Recognition or Renewal of Recognition.

DATES: Commentors should submit their written comments by August 23, 1996, to the address below.

FOR FURTHER INFORMATION CONTACT: Karen W. Kershenstein, Director, Accreditation and State Liaison Division, U.S. Department of Education, 600 Independence Avenue, SW., Room 3915 ROB–3, Washington, DC 20202–5244, telephone: (202) 708–7417. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service at 1–800–877–8339 between 8 a.m. and 7 p.m., Eastern time, Monday through Friday.

SUBMISSION OF THIRD-PARTY COMMENTS: The Secretary of Education recognizes, as reliable authorities as to the qualify of education offered by institutions or programs within their scope, accrediting agencies and State approval agencies for public postsecondary vocational education and nurse education that meet certain criteria for recognition. The purpose of this notice is to invite interested third parties to present written comments on the agencies listed in this notice that have applied for initial or continued recognition. All comments received in response to this notice will be reviewed by Department staff as part of its evaluation of the agencies' compliance with the criteria for recognition. In order for Department staff to give full consideration to the comments received, the comments must arrive at the address listed above not later than August 23 1996. Comments must relate to the Secretary's Criteria for the Recognition of Accrediting Agencies. Comments pertaining to agencies whose Interim Reports will be reviewed must be restricted to the concerns raised in the Secretary's letter for which the report is requested.

The National Advisory Committee on Institutional Quality and Integrity (the ''Advisory Committee'') advises the Secretary of Education on the recognition of accrediting agencies and State approval agencies. The Advisory Committee is scheduled to meet November 20–22, 1996 in Washington, DC. All written comments received by the Department in response to this notice will be considered by both the Advisory Committee and the Secretary. A subsequent Federal Register notice will announce the meeting and invite individuals and/or groups to submit requests for oral presentation before the Advisory Committee on the agencies being reviewed. That notice, however, does not constitute another call for written comment. This notice is the only call for written comment.

The following agencies will be reviewed during the November 1996 meeting of the Advisory Committee:

Nationally Recognized Accrediting Agencies and Associations

Petitions for Renewal of Recognition

1. Accrediting Association of Bible Colleges (requested scope of recognition: the accreditation of bible colleges and institutes offering undergraduate programs)
2. American Association of Nurse Anesthetists (requested scope of recognition: the accreditation of generic nurse anesthesia educational programs/schools)
3. Accrediting Council on Education in Journalism and Mass Communications (requested scope of recognition: the accreditation of units within institutions offering professional undergraduate and graduate (master's) degree programs)
4. The American Dietetic Association (requested scope of recognition: The accreditation of coordinated undergraduate programs in dietetics and post-baccalaureate dietetics internships)
5. American Physical Therapy Association (requested scope of recognition: the accreditation of professional programs for the physical therapist and programs for the physical therapy assistant)
6. Distance Education and Training Council (requested scope of recognition: the accreditation of home study schools, including associate, baccalaureate, or master's degree-granting home study schools)
7. Liaison Committee on Medical Education (requested scope of recognition: the accreditation programs leading to the M.D. degree)
8. Middle States Association of Colleges and Schools, Commission on Higher Education (requested scope of recognition: the accreditation of higher education institutions in Delaware, District of Columbia, Maryland, New Jersey, New York, Pennsylvania, Puerto Rico and the Virgin Islands)
9. National Environmental Health Science and Protection Accreditation Council (requested scope of recognition: the accreditation of baccalaureate programs in environmental health science and protection)
10. Transnational Association of Christian Colleges and Schools (requested scope of recognition: The accreditation of Christian postsecondary institutions that offer certificates, diplomas and associate, baccalaureate, and graduate degrees)

Interim Reports (An interim report is a follow-up report on an accrediting agency's compliance with specific criteria for recognition that was requested by the Secretary when the Secretary granted recognition to the agency)—

1. American Academy for Liberal Education
2. American Association for Marriage and Family Therapy
3. American Bar Association, Council of the Section of Legal Education and Admission to the Bar
4. American Optometric Association
5. American Podiatric Medical Association
6. Council on Naturopathic Medical Education
7. Montessori Accreditation Council for Teacher Education
8. National Accreditation Commission for Schools and Colleges of Acupuncture and Oriental Medicine
9. National Accrediting Commission of Cosmetology Arts and Sciences
10. National Association of Schools of Dance
11. National Council for Accreditation of Teacher Education
12. New York State Board of Regents

State Agencies Recognized for the Approval of Public Postsecondary Vocational Education

Petition for Renewal of Recognition

1. Oklahoma State Board of Regents for Higher Education

Interim Report

1. New York State Board of Regents (Vocational Education Unit)

State Agencies Recognized for the Approval of Nurse Education

Interim Report

1. New York State Board of Regents (Nursing Education Unit)

In accordance with the Federal policy governing the granting of academic degrees by Federal agencies (approved by letter from the Director, Bureau of the Budget, to the Secretary, Health, Education, and Welfare, dated December 23, 1954), the Secretary of Education is required to establish a review committee to advise the Secretary concerning any legislation that may be proposed which would authorize the granting of degrees by a Federal agency. The review committee forwards its recommendation concerning a Federal agency's proposed degree-granting authority to the Secretary, who then forwards the committee's recommendation to the Office of Management and Budget for review and transmittal to the Congress. The Secretary uses the Advisory Committee as the review committee required for this purpose. Accordingly, the Advisory Committee will review the following institution at its November meeting:

Proposed Bachelor's Degree-Granting Authority

1. Joint Military Intelligence College, Bolling Air Force Base (for Bachelor of Science in Intelligence)

Public Inspection of Petitions and Third-Party Comments

All petitions and interim reports, and those third-party comments received in advance of this meeting, will be available for public inspection and copying at the U.S. Department of Education, ROB–3, Room 3915, 7th and D Streets, SW., Washington, DC 20202–5244, telephone (202) 708–7417 between the hours of 8 a.m. and 4:30 p.m., Monday through Friday. It is preferred that an appointment be made in advance of such inspection or copying.

Dated: July 2, 1996.

David A. Longanecker,

Assistant Secretary for Postsecondary Education.

[FR Doc. 96–17348 Filed 7–8–96; 8:45 am]

BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

Notice of Intent to Prepare an Environmental Assessment on the Proposed Sale of Surplus Natural and Low-Enriched Uranium

AGENCY: Department of Energy.

ACTION: Notice of Intent.

SUMMARY: The Department of Energy (DOE) announces its intent to prepare an Environmental Assessment (EA) on the sale of natural uranium and low-enriched uranium located at the gaseous diffusion plants in Portsmouth, Ohio, and Paducah, Kentucky. DOE will prepare the EA pursuant to the National Environmental Policy Act of 1969 (NEPA), the Council on Environmental Quality's NEPA regulations, and the Department's NEPA regulations. The EA will describe: (1) the purpose and need for action by the Department; (2) the Department's proposed action; (3) alternatives (including a no-action alternative) to the proposed action; and (4) the potential impacts of the proposed action and alternatives.

ADDRESSES: Questions regarding this Environmental Assessment should be addressed to: Mr. John Kotek, Office of Nuclear Energy, Science and Technology, NE–1, Department of Energy, 1000 Independence Ave., SW, Washington, DC 20585. Requests to receive copies of the draft EA, when available for review, should also be directed to Mr. Kotek. Mr. Kotek may be contacted by telephone at (202) 586–6823, or by facsimile at (202) 586–0698.

DATES: DOE anticipates that it will issue a draft EA by July 30, 1996, which it will forward for review by affected states, Indian tribes, and other parties who have expressed an interest in the proposed action or requested a copy of the draft for review. The Department will accept comments on the EA for 30 days following issuance of the draft EA.

FOR FURTHER INFORMATION CONTACT: For general information on DOE's NEPA process, contact Ms. Carol M. Borgstrom, Director, Office of NEPA Policy and Assistance, EH–42, Department of Energy, 1000 Independence Ave. SW, Washington, DC 20585. Ms. Borgstrom may be contacted by leaving a message at (800) 472–2756 or by calling (202) 586–4600.

SUPPLEMENTARY INFORMATION:

Background

DOE owns substantial amounts of natural uranium and low-enriched uranium (LEU) in excess of the Department's current needs. The Department has declared about 21.5 million pounds of these materials to be surplus. About 20.3 million pounds of these materials contain the uranium isotope U-235 in concentrations (0.711 percent) equivalent to natural uranium; about 1.2 million pounds contain U-235 concentration of 4.5 percent, and are therefore classified as LEU. The LEU is stored at the gaseous diffusion plant in Portsmouth, Ohio; the 20.3 million pounds of natural uranium are stored at Paducah, Kentucky. In addition to these 21.5 million pounds, the Department will receive title to another 14.2 million pounds of natural uranium associated with the United States/Russia Highly Enriched Uranium Purchase Agreement (Russian HEU Agreement).[1] These 14.2 million pounds are located at the Paducah gaseous diffusion plant and will remain under the control and ownership of the United States Enrichment Corporation (USEC) until ownership is transferred to DOE before the end of 1996.

Congress has imposed a number of requirements on the sale and use of these materials. Section 3112(b)(1) of the United States Enrichment Corporation Privatization Act of 1996 (USEC Privatization Act, Public Law 104–134) requires that DOE sell within seven years the 14.2 million pounds of natural uranium associated with the U.S./Russia HEU Agreement. Under section 3112(b)(2), DOE may sell this natural uranium: (1) for overfeeding of enrichment operations in the United States at any time; (2) for end use outside of the United States at any time; (3) to the Russian Executive Agent in 1995 and 1996 for use in matched sales pursuant to the Suspension Agreement;[2] or (4) in 2001 for end use in the United States beginning in 2002 in amounts not to exceed 3 million pounds annually.

As to the 21.5 million pounds of natural uranium and low-enriched uranium DOE already has in its inventory, Congress did not mandate

[1] In the U.S./Russia HEU Agreement, the United States and Russia agreed that USEC, as the United States' Executive Agent, would purchase low-enriched uranium derived from 500 metric tons of highly enriched uranium extracted from nuclear weapons dismantled in Russia.

[2] The Suspension Agreement, also referred to as the ''Agreement to Suspend Investigation on Uranium from the Russia Federation, as amended,'' settled an investigation into whether Russia was dumping uranium into the United States market. It established a mechanism known as ''matched sales arrangements'' in which imports of Russian uranium are linked with sales of uranium newly produced in the United States. In a matched sale, one-half of the uranium sold is Russian and the other one-half is new domestic production. There are annual quotas on the amount of matched sales through 2004, when the Suspension Agreement expires.

that the Department sell these materials within a particular period of time. However, Congress anticipated in the Energy and Water Development Appropriations Act of 1996 that DOE would sell about $35 million worth of these materials in fiscal year 1996 and use the proceeds to offset some of the costs of maintaining and improving the gaseous diffusion plants. The Department believes that it will need to sell additional amounts of these materials beginning in 1996 in order to continue financing maintenance and other activities at the gaseous diffusion plants.

Congress imposed three conditions on the sale of material from DOE's inventory in section 3112(d) of the USEC Privatization Act; two of these conditions are relevant to the 21.5 million pounds of inventory material considered in this Environmental Assessment. Before selling materials from DOE's inventory, the Secretary of Energy must make a determination that: (1) the sale will not have an ''adverse material impact'' on the domestic uranium industry and (2) the Department will receive a price that is at least equal to the fair market value of the materials.

Proposed Action

DOE proposes to sell the 21.5 million pounds of surplus material in its inventory and the 14.2 million pounds of material associated with the Russian HEU Agreement that the Department will receive from USEC. All of the 35.7 million pounds are in the form of uranium hexafluoride (UF_6). DOE proposes to sell these 35.7 million pounds of uranium over six or more years beginning in 1996. The potential buyers are entities that already purchase or manage inventories of uranium for use in commercial applications: USEC, utilities, convertors, brokers and uranium producers. Accordingly, the proposed action would not result in new or different uses of uranium.

DOE would comply with sections 3112 (b) and (d) of the USEC Privatization Act in making the sales it is proposing. In 1996, DOE proposes to sell some of the 14.2 million pounds it will receive under the Russian HEU Agreement to the Russian Executive Agent, or the Agent's representative, for use in matched sales pursuant to the Suspension Agreement. The Department would sell, to the extent practical, the remainder of this 14.2 million pounds for end use outside the United States or for overfeeding the gaseous diffusion plants during the period 1997 through 2000. Any remaining material would be sold in 2001 for consumption by domestic end users beginning in 2002 at a rate not to exceed 3 million pounds per year. As to the 21.5 million pounds from DOE's inventory, the Department proposes to sell the one million pounds of LEU in 1996 in order to obtain the revenue Congress anticipated DOE would receive in the Energy and Water Development Appropriations Act of 1996. DOE would sell the remaining 20.3 million pounds of inventory materials during the period 1997 through 2002 in order to continue financing maintenance and other activities at the gaseous diffusion plants. All sales of inventory materials would be contingent on the Secretary making the determinations required by section 3112(d)(2) of the USEC Privatization Act.

The sales proposed and evaluated in this Environmental Assessment would be in addition to sales evaluated in two other NEPA analyses: (1) the Disposition of Surplus Highly Enriched Uranium Final EIS (DOE/EIS—0240, June 1996), and (2) the Environmental Assessment for the Purchase of Russian Low Enriched Uranium Derived from the Dismantlement of Nuclear Weapons in the Countries of the Former Soviet Union (USEC/EA—94001, DOE/EA—0837, January 1994). The Department will analyze the cumulative effects of the sales proposed in this environmental assessment, those proposed in the two other NEPA analyses, and those scheduled under the Russian HEU Agreement and the Suspension Agreement.

Alternatives

DOE has identified alternatives to its proposed sale of these materials, and may identify others during the preparation of the EA. All alternatives will be evaluated against the purpose and need for action by the Department, and those that are reasonable and meet the need for action by the Department will be evaluated in the EA.

No Action

The Council on Environmental Quality's NEPA regulations require that federal agencies analyze the impacts of not taking the proposed action (the ''No Action Alternative''). In this case, the No Action Alternative would be that DOE would continue to store the 35.7 million pounds of uranium at Portsmouth and Paducah rather than selling it.

Alternatives that Satisfy the Need for Department Action

Alternatives that are under consideration for evaluation in the EA include:

(1) Different schedules for the sale of this uranium; and

(2) Selling amounts other than 21.5 million pounds of inventory material.

Preliminary Identification of Potential Environmental Impacts

The Department has tentatively identified the following potential impacts for evaluation in the EA. This list is not intended to be all-inclusive or to predetermine the potential impacts of any of the alternatives.

(1) Potential health and safety impacts to on-site workers and to the public from storage, handling, and transport of uranium, including accidents;

(2) Socioeconomic impacts on the uranium industry in the United States;

(3) Potential cumulative impacts of these and other sales; and

(4) Considerations of environmental justice.

DOE anticipates that it will issue a draft EA by July 30, 1996, which it will forward for review by affected states, Indian tribes, and other parties who have expressed an interest in the proposed action or requested a copy of the draft for review. The Department will accept comments on the EA for 30 days following issuance of the draft EA. Based on the EA and any comments it receives, DOE will then determine whether it will prepare an environmental impact statement or issue a finding of no significant impact.

Issued in Washington, D.C., this 1st day of July, 1996, for the United States Department of Energy.

Ray A. Hunter,

Deputy Director, Office of Nuclear Energy, Science and Technology.

[FR Doc. 96–17432 Filed 7–8–96; 8:45 am]

BILLING CODE 6450–01–P

Environmental Management Site-Specific Advisory Board, Pantex Plant; Meeting

AGENCY: Department of Energy.

ACTION: Notice of Open Meeting.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Public Law 92–463, 86 Stat. 770) notice is hereby given of the following Advisory Committee meeting: Environmental Management Site-Specific Advisory Board (EM SSAB), Pantex Plant.

DATE AND TIME: Tuesday, July 23, 1996: 10:00 a.m.–2:00 p.m.

ADDRESSES: Carson County Square House Museum, 5th and Elsie, Panhandle, Texas.

FOR FURTHER INFORMATION CONTACT: Tom Williams, Program Manager,

Department of Energy, Amarillo Area Office, P.O. Box 30030, Amarillo, TX 79120, (806)477–3121.

SUPPLEMENTARY INFORMATION: *Purpose of the Committee:* The Board provides input to the Department of Energy on Environmental Management strategic decisions that impact future use, risk management, economic development, and budget prioritization activities.

Tentative Agenda:

10:00 am Welcome—Agenda Review—Approval of Minutes
10:15 am Co-Chairs' Comments
10:45 am Subcommittee Reports
Community Outreach
Budget and Finance
Nominations
Program and Training
Policy and Personnel
11:15 am Updates
Occurrence Reports—DOE
Gerald Johnson Update
Pantex Fatality Update, Paul Sowa
12:00 pm Lunch
12:30 pm Presentation
1:30 pm Task Force Reports
Site-wide Environmental Impact Statement
Environmental Restoration
2:00 pm Adjourn

Public Participation: The meeting is open to the public. Written statements may be filed with the Committee either before or after the meeting. Written comments will be accepted at the address above for 15 days after the date of the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Tom Williams' office at the address or telephone number listed above. Requests must be received 5 days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Designated Federal Official is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of 5 minutes to present their comments.

Minutes: The minutes of this meeting will be available for public review and copying at the Pantex Public Reading Rooms located at the Amarillo College Lynn Library and Learning Center, 2201 South Washington, Amarillo, TX phone (806) 371–5400. Hours of operation are from 7:45 am to 10:00 pm, Monday through Thursday; 7:45 am to 5:00 pm on Friday; 8:30 am to 12:00 noon on Saturday; and 2:00 pm to 6:00 pm on Sunday, except for Federal holidays. Additionally, there is a Public Reading Room located at the Carson County Public Library, 401 Main Street, Panhandle, TX phone (806) 537–3742. Hours of operation are from 9:00 am to 7:00 pm on Monday; 9:00 am to 5:00 pm, Tuesday through Friday; and closed Saturday and Sunday as well as Federal Holidays. Minutes will also be available by writing or calling Tom Williams at the address or telephone number listed above.

Issued at Washington, DC on July 3, 1996.

Rachel M. Samuel,

Acting Deputy Advisory Committee Management Officer.

[FR Doc. 96–17433 Filed 7–08–96; 8:45 am]

BILLING CODE 6450–01–P

Federal Energy Regulatory Commission

Information Collection Submitted for Review and Request for Comments (FERC–598)

July 2, 1996.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of submission for review by the Office of Management and Budget (OMB) and request for comments.

SUMMARY: In compliance with the requirements of Section 3507 of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), the Federal Energy Regulatory Commission (Commission) is submitting a collection of information listed in this notice to OMB for review under the provisions of the Act.

DATES: Comments regarding this collection of information are best assured of having their full effect if received within 30 days of this notification.

ADDRESSES: Copies of the collection of information can be obtained from and written comments may be submitted to the Federal Energy Regulatory Commission, Attn: Michael P. Miller, Information Services Division, ED–12.4, 888 First Street N.E., Washington, D.C. 20426. Comments should also be addressed to: Desk Officer, Federal Energy Regulatory Commission, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, D.C. 20503.

FOR FURTHER INFORMATION CONTACT: Michael P. Miller may be reached by telephone at (202) 208–1415, by fax at (202) 273–0873, and by e-mail at mmiller@ferc.fed.us.

SUPPLEMENTARY INFORMATION:

Abstract

The information collected under the requirements of FERC–598 ''Determinations for Entities Seeking Exempt Wholesale Generator Status'' OMB No. 1902–0166) is used by the Commission to implement the statutory provisions of Section 711 of the Energy Policy Act of 1992 (EPAct), Public Law 102–46 which amended the Public Utility Holding Company Act of 1935 (PUHCA) to create a category of power producers. Section 2(a)(11)(B) define an EWG as an entity engaged directly, or indirectly through one or more affiliates in the business exclusively of owning and/or operating all or part of one or more eligible facilities, and selling electric energy at wholesale. The Commission implements these filing requirements in the code of Federal Regulations (CFR) under 18 CFR Part 365.

Action

The Commission is requesting a three-year extension of the current expiration date, with no changes to the existing collection of data. The Commission did not receive any comments in response to the public notice published in the Federal Register, April 12, 1996 (61 FR, 16904–05).

Burden Statement

Public reporting burden for this collection is estimated as

No. of respondents annually (1)	No. of responses per respondent (2)	Average burden hours per response (3)	Total annual burden hours (1)×(2)×(3)
280	1	6 hours	1,680 hours.

Estimated cost burden to respondents: 1,680 hours/2,087 hours per year × $102,000 per year = $82,108.

The reporting burden includes the total time, effort, or financial resources expended to generate, maintain, retain, disclose, or provide the information including: (1) reviewing instructions; (2) developing, acquiring, installing, and utilizing technology and systems for the purposes of collecting, validating, verifying, processing, maintaining, disclosing and providing information; (3) adjusting the existing ways to comply with any previously applicable instructions and requirements; (4) training personnel to respond to a collection of information; (5) searching data sources; (6) completing and reviewing the collection of information; and (7) transmitting, or otherwise disclosing the information.

The estimate of cost for respondents is based upon salaries for professional and clerical support, as well as direct and indirect overhead costs. Direct costs include all costs directly attributable to providing this information, such as administrative costs and the cost for information technology. Indirect or overhead costs are costs incurred by an organization in support of its mission. These costs apply to activities which benefit the whole organization rather than any one particular function or activity.

Lois D. Cashell,

Secretary.

[FR Doc. 96–17405 Filed 7–8–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP96–595–000]

El Paso Natural Gas Company; Notice of Request Under Blanket Authorization

July 2, 1996.

Take notice that on June 25, 1996, El Paso Natural Gas Company (El Paso), P.O. Box 1492, El Paso, Texas 79978, filed in Docket No. CP96–595–000, a request pursuant to Sections 157.205 and 157.212 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205 and 157.212) for authorization to upgrade and relocate the existing Chandler No. 3 Meter Station (meter station) located in Maricopa, Arizona, under Northern's blanket certificate issued in Docket No. CP82–432–000 and Section 7(c) of the Natural Gas Act, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

El Paso proposes to upgrade and relocate a meter station to make additional firm deliveries of natural gas to Southwest Gas Corporation (Southwest) for service to Chandler, Arizona, and environs. El Paso asserts that Southwest has requested additional firm service and that the present meter station is unable to accommodate such delivery. It is further asserted that, by letter agreement dated November 22, 1994, El Paso and Southwest have agreed that El Paso would therefore upgrade the existing meter station. El Paso states that, in order to facilitate ease of maintenance and to eliminate a potentially hazardous situation, El Paso has elected to relocate the existing meter station approximately 53 feet north on the Tucson-Phoenix Line and the Tucson-Phoenix Loop Line.

It is indicated that the proposed quantity of natural gas to be transported on a firm basis to the upgraded meter station is estimated to be 511,636 Mcf annually during the third full year of operation. It is further indicated that the estimated maximum peak day gas requirement at the meter station during the third calendar year of service is 13,680 Mcf. El Paso asserts the gas will be used by Southwest to satisfy the residential, residential space heating, commercial, commercial space heating, and the industrial requirements of customers in Chandler, Arizona, and environs. El Paso states that the proposed firm transportation of gas to Southwest at the meter station will have a negligible effect on El Paso's 1995 peak day and total annual transportation quantities. El Paso further states that estimated cost of the proposed facilities is $101,500, which Southwest has agreed to reimburse El Paso.

Any person or the Commission Staff may, within 45 days of the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.214), a motion to intervene 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 therefore, the proposed activities 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 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. 96–17346 Filed 7–8–96; 8:45 am]

BILLING CODE 6717–01M

[Docket No. CP96–610–000]

Granite State Gas Transmission, Inc.; Notice of Application

July 2, 1996.

Take notice that on July 1, 1996, Granite State Gas Transmission, Inc. (Granite State), 300 Friberg Parkway, Westborough, Massachusetts 01581, filed in Docket No. CP96–610–000, an application pursuant to Section 7(c) of the Natural Gas Act and Part 157 of the Commission's Regulations for a certificate of public convenience and necessity authorizing the construction and operation of a liquefied natural gas (LNG) facility in Wells, Maine, to serve Northern Utilities, Inc. (Northern Utilities), pursuant to new Rate Schedule LNG–1, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Granite State submits that the LNG facility proposed in this application is identical to the one proposed in Docket No. CP–95–52–000, that was dismissed without prejudice to resubmitting the proposal changing its use from baseload to peakshaving service. According to Granite State, this resubmitted filing reflects a change in the nature of the service to be provided by such facility from winter baseload to peakshaving.

Granite State further states that the LNG facility is necessary to replace Northern Utilities' volumes currently flowing using capacity leased on the Portland Pipe Line Corporation's oil line that has been converted to natural gas use. According to Granite State, the lease is set to expire on April 30, 1998, and Granite State proposes an in-service date of November 1, 1998 for the proposed LNG facility, the first day of the first heating season after the lease expires.

Granite State states that Northern Utilities has contracted for transportation service on the Portland Natural Gas Transmission System (PNGTS) which also has a proposed in-service date of November 1, 1998. However, Granite State maintains that the LNG facility may be necessary for winter baseload service for Northern Utilities if PNGTS is not in service by that date. After PNGTS is in service, the LNG facility would provide peakshaving service to Northern Utilities.

According to information contained in the application, once the LNG facility is functioning as a peakshaver it would be operated in a fashion that would allow deliverability from the facility to increase by almost 150%. Accordingly, Granite State's resubmitted filing contains a revised precedent agreement

with Northern Utilities which provides for a maximum daily deliverability from the LNG facility of 54,640 Dth per day prior to PNGTS, and 134,000 Dth per day thereafter. Although not explicitly stated by Granite State in its proposal, based upon the volumetric determinants contained in Exhibit P of the application, these maximum withdrawal levels would translate to a 52-day service prior to PNGTS, and 12–13 days of service afterwards.

Any person desiring to be heard or to make any protest with reference to said application should on or before July 23, 1996 file with the Federal Energy Regulatory Commission, Washington, D.C. 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 is 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 Granite State to appear or be represented at the hearing.

Lois D. Cashell,

Secretary.

[FR Doc. 96–17410 Filed 7–8–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. MG96–13–001]

K N Interstate Gas Transmission Company; Notice of Filing

July 2, 1996.

Take notice that on June 27, 1996, K N Interstate Gas Transmission Company (K N Interstate) submitted a ''Motion of K N Interstate Gas Transmission Company for Authorization to Withdraw and Substitute Revised Statement on Standard of Conduct.'' K N Interstate states that it ''inadvertently filed an earlier, incorrect version of the Revised Standards with the Commission.'' K N Interstate states that it is filing the revised standards of conduct in compliance with Order Nos. 497 *et seq.*[1] and Order Nos. 566, *et seq.*[2]

K N Interstate states that copies of this filing have been mailed to all parties on the official service list compiled by the Secretary in this proceeding.

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, 888 First Street, N.E., Washington, D.C., 20426, in accordance with Rules 211 or 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 or 385.214). All such motions to intervene or protest should be filed on or before July 17, 1996. 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. 96–17347 Filed 7–8–96; 8:45 am]

BILLING CODE 6717–01–M

[1] Order No. 497, 53 FR 22139 (June 14, 1988), III FERC Stats. & Regs. ¶ 30,820 (1988); Order No. 497–A, *order on rehearing*, 54 FR 52781 (December 22, 1989), III FERC Stats. & Regs. 30,868 (1989); Order No. 497–B, *order extending sunset date*, 55 FR 53291 (December 28, 1990), III FERC Stats. & Regs. ¶ 30,908 (1990); Order No. 497–C, *order extending sunset date*, 57 FR 9 (January 2, 1992), III FERC Stats. & Regs. ¶ 30,934 (1991), rehearing denied, 57 FR 5815 (February 18, 1992), 58 FERC ¶ 61,139 (1992); Tenneco Gas v. FERC (affirmed in part and remanded in part), 969 F. 2d 1187 (D.C. Cir. 1992); Order No. 497–D, *order on remand and extending sunset date*, III FERC Stats. & Regs. ¶ 30,958 (December 4, 1992), 57 FR 58978 (December 14, 1992); Order No. 497–E, *order on rehearing and extending sunset date*, 59 FR 243 (January 4, 1994), 65 FERC ¶ 61,381 (December 23, 1993); Order No. 497–F, *order denying rehearing and granting clarification*, 59 FR 15336 (April 1, 1994), 66 FERC ¶ 61,347 (March 24, 1994); and Order No. 497–G, *order extending sunset date*, 59 FR 32884 (June 27, 1994), III FERC Stats. & Regs. ¶ 30,996 (June 17, 1994).

[2] Standards of Conduct and Reporting Requirements for Transportation and Affiliate Transactions, Order No. 566, 59 FR 32885 (June 27, 1994), III FERC Stats. & Regs. ¶ 30, 997 (June 17, 1994); Order No. 566–A, *order on rehearing*, 59 FR 52896 (October 20, 1994), 69 FERC ¶ 61,044 (October 14, 1994), Order No. 566–B, *order on rehearing*, 59 FR 65707 (December 21, 1994); 69 FERC ¶ 61,334 (December 14, 1994).

FEDERAL ENERGY REGULATORY COMMISSION

[Docket No. ER96–2223–000, et al.]

New England Power Company, et al. Electric Rate and Corporate Regulation Filings

July 1, 1996.

Take notice that the following filings have been made with the Commission:

1. New England Power Company

[Docket No. ER96–2223–000]

Take notice that on June 25, 1996, New England Power Company, filed a Service Agreement and Certificate of Concurrence with TransCanada Power Corp. under NEP's FERC Electric Tariff, Original Volume No. 5.

Comment date: July 15, 1996, in accordance with Standard Paragraph E at the end of this notice.

2. Jersey Central Power & Light Company, Metropolitan Edison Company, Pennsylvania Electric Company

[Docket No. ER96–2224–000]

Take notice that on June 25, 1996, GPU Service Corporation (GPU), on behalf of Jersey Central Power & Light Company, Metropolitan Edison Company and Pennsylvania Electric Company (jointly referred to as the GPU Operating Companies), filed an executed Service Agreement between GPU and AIG Trading Corporation (AIG), dated June 18, 1996. This Service Agreement specifies that AIG has agreed to the rates, terms and conditions of the GPU Operating Companies' Operating Capacity and/or Energy Sales Tariff (Sales Tariff) designated as FERC Electric Tariff, Original Volume No. 1. The Sales Tariff was accepted by the Commission by letter order issued on February 10, 1995 in *Jersey Central Power & Light Co., Metropolitan Edison Co. and Pennsylvania Electric Co.,* Docket No. ER95–276–000 and allows GPU and AIG to enter into separately scheduled transactions under which the GPU Operating Companies will make available for sale, surplus operating capacity and/or energy at negotiated rates that are no higher than the GPU Operating Companies' cost of service.

GPU requests a waiver of the Commission's notice requirements for

good cause shown and an effective date of June 18, 1996 for the Service Agreement.

GPU has served copies of the filing on regulatory agencies in New Jersey and Pennsylvania.

Comment date: July 15, 1996, in accordance with Standard Paragraph E at the end of this notice.

3. Portland General Electric Company

[Docket No. ER96–2225–000]

Take notice that on June 25, 1996, Portland General Electric Company (PGE), tendered for filing an Amendment No. 1 to the Power Sales Agreement between PGE and the Canby Utility Board (PGE Rate Schedule FERC No. 192). The Amendment deletes certain definition in the original agreement pertaining to price determinations, changes the termination date of the original agreement and sets forth pricing for each Billing Month effective August 1, 1996 until September 30, 2001.

Pursuant to 18 CFR 35.11, PGE respectfully requests the Commission grant a waiver of the notice requirements of 18 CFR 35.3 to allow Amendment No. 1 to PGE Rate Schedule FERC No. 192 to become effective August 1, 1996.

Copies of this filing were served upon the names listed in the filing letter.

Comment date: July 15, 1996, in accordance with Standard Paragraph E at the end of this notice.

4. Tampa Electric Company

[Docket No. ER96–2226–000]

Take notice that on June 25, 1996, Tampa Electric Company (Tampa Electric), tendered for filing an amendment to its contract for the sale and purchase of capacity and energy with Georgia Power Company (Georgia Power).

Tampa Electric proposes that the amendment be made effective on July 9, 1996, and therefore requests a waiver of the Commission's notice requirement.

Copies of the filing have been served on Georgia Power and the Florida and Georgia Public Service Commission.

Comment date: July 15, 1996, in accordance with Standard Paragraph E at the end of this notice.

5. Tampa Electric Company

[Docket No. ER96–2227–000]

Take notice that on June 25, 1996, Tampa Electric Company (Tampa Electric), tendered for filing a Letter Agreement that amends the existing Letter of Commitment between Tampa Electric and the Utilities Commission, City of New Smyrna Beach, Florida (New Smyrna Beach) under interchange Service Schedule D.

Tampa Electric proposes that the Letter Agreement be made effective on July 9, 1996, and therefore requests waiver of the Commission's notice requirement.

Copies of the filing have been served on New Smyrna Beach and the Florida Public Service Commission.

Comment date: July 15, 1996, in accordance with Standard Paragraph E at the end of this notice.

6. Consolidated Edison Company of New York, Inc.

[Docket No. ER96–2228–000]

Take notice that on June 25, 1996, Consolidated Edison Company of New York, Inc. (Con Edison), tendered for filing an agreement to provide interruptible transmission service for DuPont Power Marketing, Inc. (DuPont).

Con Edison states that a copy of this filing has been served by mail upon DuPont.

Comment date: July 15, 1996, in accordance with Standard Paragraph E at the end of this notice.

7. Consolidated Edison Company of New York, Inc.

[Docket No. ER96–2229–000]

Take notice that on June 25, 1996, Consolidated Edison Company of New York, Inc. (Con Edison), tendered for filing an agreement to provide interruptible transmission service for AIG Trading Corporation (AIG).

Con Edison states that a copy of this filing has been served by mail upon AIG.

Comment date: July 15, 1996, in accordance with Standard Paragraph E at the end of this notice.

8. Niagara Mohawk Power Corporation

[Docket No. ER96–2230–000]

Take notice that on June 25, 1996, Niagara Mohawk Power Corporation (NMPC), tendered for filing with the Federal Energy Regulatory Commission executed Service Agreements between NMPC and The Cleveland Electric Illuminating Company, and The Toledo Edison Company (Cleveland and Toledo). These Service Agreements specify that Cleveland and Toledo have signed on to and have agreed to the terms and conditions of NMPC's Power Sales Tariff designated as NMPC's FERC Electric Tariff, Original Volume No. 2. This Tariff, approved by FERC on April 15, 1994, and which has an effective date of March 13, 1993, will allow NMPC and Cleveland and Toledo to enter into separately scheduled transactions under which NMPC will sell to Cleveland and Toledo capacity and/or energy as the parties may mutually agree.

In its filing letter, NMPC also included a Certificate of Concurrence executed by the Purchasers.

NMPC has served copies of the filing upon the New York State Public Service Commission and Cleveland and Toledo.

Comment date: July 15, 1996, in accordance with Standard Paragraph E at the end of this notice.

9. Niagara Mohawk Power Corporation

[Docket No. ER96–2231–000]

Take notice that on June 25, 1996, Niagara Mohawk Power Corporation (NMPC), tendered for filing with the Federal Energy Regulatory Commission, an executed Service Agreement between NMPC and Duke/Louis Dreyfus LLC (D/LD). This Service Agreement specifies that D/LD has signed on to and has agreed to the terms and conditions of NMPC's Power Sales Tariff designated as NMPC's FERC Electric Tariff, Original Volume No. 2. This Tariff, approved by FERC on April 15, 1994, and which has an effective date of March 13, 1993, will allow NMPC and D/LD to enter into separately scheduled transactions under which NMPC will sell to D/LD capacity and/or energy as the parties may mutually agree.

In its filing letter, NMPC also included a Certificate of Concurrence executed by the Purchaser.

NMPC requests an effective date of June 17, 1996. NMPC has requested waiver of the notice requirements for good cause shown.

NMPC has served copies of the filing upon the New York State Public Service Commission and D/LD.

Comment date: July 15, 1996, in accordance with Standard Paragraph E at the end of this notice.

10. Niagara Mohawk Power Corporation

[Docket No. ER96–2232–000]

Take notice that on June 25, 1996, Niagara Mohawk Power Corporation (NMPC), tendered for filing with the Federal Energy Regulatory Commission, an executed Service Agreement between NMPC and AIG Trading Corporation (AIG). This Service Agreement specifies that AIG has signed on to and has agreed to the terms and conditions of NMPC's Power Sales Tariff designated as NMPC's FERC Electric Tariff, Original Volume No. 2. This Tariff, approved by FERC on April 15, 1994, and which has an effective date of March 13, 1993, will allow NMPC and AIG to enter into separately scheduled transactions under which NMPC will

sell to AIG capacity and/or energy as the parties may mutually agree.

In its filing letter, NMPC also included a Certificate of Concurrence executed by the Purchaser.

NMPC requests an effective date of June 17, 1996. NMPC has requested waiver of the notice requirements for good cause shown.

NMPC has served copies of the filing upon the New York State Public Service Commission and AIG.

Comment date: July 15, 1996, in accordance with Standard Paragraph E at the end of this notice.

11. Niagara Mohawk Power Corporation

[Docket No. ER96–2233–000]

Take notice that on June 25, 1996, Niagara Mohawk Power Corporation (NMPC), tendered for filing with the Federal Energy Regulatory Commission, an executed Service Agreement between NMPC and Coral Power, LLC (Coral). This Service Agreement specifies that Coral has signed on to and has agreed to the terms and conditions of NMPC's Power Sales Tariff designated as NMPC's FERC Electric Tariff, Original Volume No. 2. This Tariff, approved by FERC on April 15, 1994, and which has an effective date of March 13, 1993, will allow NMPC and Coral to enter into separately scheduled transactions under which NMPC will sell to Coral capacity and/or energy as the parties may mutually agree.

In its filing letter, NMPC also included a Certificate of Concurrence executed by the Purchaser.

NMPC requests an effective date of June 17, 1996. NMPC has requested waiver of the notice requirements for good cause shown.

NMPC has served copies of the filing upon the New York State Public Service Commission and Coral.

Comment date: July 15, 1996, in accordance with Standard Paragraph E at the end of this notice.

12. Niagara Mohawk Power Corporation

[Docket No. ER96–2234–000]

Take notice that on June 25, 1996, Niagara Mohawk Power Corporation (NMPC), tendered for filing with the Federal Energy Regulatory Commission, an executed Service Agreement between NMPC and MidCon Power Services Corporation (MidCon). This Service Agreement specifies that MidCon has signed on to and has agreed to the terms and conditions of NMPC's Power Sales Tariff designated as NMPC's FERC Electric Tariff, Original Volume No. 2. This Tariff, approved by FERC on April 15, 1994, and which has an effective date of March 13, 1993, will allow NMPC and MidCon to enter into separately scheduled transactions under which NMPC will sell to MidCon capacity and/or energy as the parties may mutually agree.

In its filing letter, NMPC also included a Certificate of Concurrence executed by the Purchaser.

NMPC requests an effective date of June 17, 1996. NMPC has requested waiver of the notice requirements for good cause shown.

NMPC has served copies of the filing upon the New York State Public Service Commission and MidCon.

Comment date: July 15, 1996, in accordance with Standard Paragraph E at the end of this notice.

13. Niagara Mohawk Power Corporation

[Docket No. ER96–2235–000]

Take notice that on June 25, 1996, Niagara Mohawk Power Corporation (NMPC), tendered for filing with the Federal Energy Regulatory Commission, an executed Service Agreement between NMPC and TransCanada Power Corporation (TransCanada). This Service Agreement specifies that TransCanada has signed on to and has agreed to the terms and conditions of NMPC's Power Sales Tariff designated as NMPC's FERC Electric Tariff, Original Volume No. 2. This Tariff, approved by FERC on April 15, 1994, and which has an effective date of March 13, 1993, will allow NMPC and TransCanada to enter into separately scheduled transactions under which NMPC will sell to TransCanada capacity and/or energy as the parties may mutually agree.

In its filing letter, NMPC also included a Certificate of Concurrence executed by the Purchaser.

NMPC requests an effective date of June 17, 1996. NMPC has requested waiver of the notice requirements for good cause shown.

NMPC has served copies of the filing upon the New York State Public Service Commission and TransCanada.

Comment date: July 15, 1996, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraph

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, 888 First 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. 96–17406 Filed 7–8–96; 8:45 am]

BILLING CODE 6717–01–P

Federal Energy Regulatory Commission

[Docket No. EG96–77–000, et al.]

NRGenerating Holdings (No. 3) B.V., et al; Electric Rate and Corporate Regulation Filings

June 28, 1996.

Take notice that the following filings have been made with the Commission:

1. NRGenerating Holdings (No. 3) B.V.

[Docket No. EG96–77–000]

On June 19, 1996, NRGenerating Holdings (No. 3) B.V. (''Applicant''), with its principal office at c/o NRG Energy, Inc., Level 50, Rialto South Tower, 525 Collins Street, Melbourne Victoria 3000, Australia, filed with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's Regulations.

Applicant states that it holds an interest in an unincorporated joint venture to be formed under the laws of Australia to acquire, own and operate a 1,600 megawatt brown coal-fired electric generating facility and adjacent brown coal open cut mine located in Victoria, Australia (the ''Facility''). Electric energy produced by the Facility will be sold at wholesale to the Victoria Power Exchange. In no event will any electric energy be sold to consumers in the United States.

Comment date: July 15, 1996, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

2. NRGenerating Holdings (No. 4) B.V.

[Docket No. EG96–78–000]

On June 19, 1996, NRGenerating Holdings (No. 4) B.V. (''Applicant''), with its principal office at c/o NRG Energy, Inc., Level 50, Rialto South

Tower, 525 Collins Street, Melbourne Victoria 3000, Australia, filed with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's Regulations.

Applicant states that it holds an interest in an unincorporated joint venture to be formed under the laws of Australia to acquire, own and operate a 1,600 megawatt brown coal-fired electric generating facility and adjacent brown coal open cut mine located in Victoria, Australia (the ''Facility''). Electric energy produced by the Facility will be sold at wholesale to the Victoria Power Exchange. In no event will any electric energy be sold to consumers in the United States.

Comment date: July 15, 1996, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accruacy of the application.

3. Public Service Company of New Mexico

[Docket No. EL96–16–000]

Take notice that on May 28, 1996, Public Service Company of New Mexico tendered for filing an amendment in the above-referenced docket.

Comment date: July 16, 1996, in accordance with Standard Paragraph E at the end of this notice.

4. North Carolina Utilities Commission

[Docket No. EL96–58–000]

Take notice that on June 11, 1996, the North Carolina Utilities Commission tendered for filing a Petition for Waiver on behalf of Nantahala Power and Light Company (Nantahala) pursuant to Section 292.402 of the Commission's Regulations, to request that the Commission grant to Nantahala a waiver of the application of Section 292.303(a) of the Commission's Regulations, concerning purchases from qualifying facilities under the Public Utility Regulatory Policies Act of 1978.

Comment date: July 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

5. Louisville Gas & Electric Company

[Docket No. ER96–1853–000]

Take notice that on June 11, 1996, Louisville Gas & Electric Company tendered for filing an amendment in the above-referenced docket.

Comment date: July 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

6. Delmarva Power & Light Company

[Docket No. ER96–1962–000]

Take notice that on June 25, 1996, Delmarva Power & Light Company (Delmarva) tendered for filing a Revised Supplement to its FERC Rate Schedule No. 99, with respect to Delmarva's partial requirements service agreement with the City of Seaford. The Revised Supplement corrects an error in its application filed May 31, 1996. The Revised Supplement proposes a rate change that would increase base demand and energy rates by 1.19%, or about $17,000 annually.

Delmarva proposes an effective date of June 1, 1996. Delmarva asserts that the increase and the proposed effective date is in accord with the service agreement with the City of Seaford as accepted for filing as Rate Schedule No. 99 and eight supplements in Docket No. ER95–1039–000, which service agreement provides for changes in rates that correspond to the level of changes in rates approved by the Delaware Public Service Commission for Delmarva's non-residential retail customers.

Copies of the filing were served on the City of Seaford and the Delaware Public Service Commission.

Comment date: July 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

7. Florida Power & Light Company

[Docket No. ER96–1001–000]

Take notice that on June 12, 1996, Florida Power & Light Company tendered for filing an amendment in the above referenced docket.

Comment date: July 11, 1996, in accordance with Standard Paragraph E at the end of this notice.

8. Southern Company Services, Inc.

[Docket No. ER96–2179–000]

Take notice that on June 19, 1996, Southern Company Services, Inc., acting on behalf of Alabama Power Company, Georgia Power Company, Gulf Power Company, Mississippi Power Company and Savannah Electric and Power Company (collectively the ''Southern Companies'') filed a Short-Term Transaction Service Agreement by and among itself, as agent for the Southern Companies and Saluda River Electric Cooperative, Inc. pursuant to which Southern Companies will make wholesale power sales for transactions of less than one (1) year in duration.

Comment date: July 11, 1996, in accordance with Standard Paragraph E at the end of this notice.

9. Illinois Power Company

[Docket No. ER96–2186–000]

Take notice that on May 31, 1996, Illinois Power Company tendered for filing a summary of its activity for April 1996, under its Market Based Rate Tariff, FERC Electric Tariff, Original Volume No. 7 (Original Sheet Nos. 1–11).

Comment date: July 11, 1996, in accordance with Standard Paragraph E at the end of this notice.

10. Midwest Energy Inc.

[Docket No. ER96–2187–000]

Take notice that on June 19, 1996, Midwest Energy Inc. tendered for filing a Service Agreement for Firm Transmission Service with the City of Hill City, Kansas.

Comment date: July 11, 1996, in accordance with Standard Paragraph E at the end of this notice.

11. American Electric Power Service Corporation

[Docket No. ER96–2213–000]

Take notice that on June 24, 1996, American Electric Power Service Corporation, on behalf of Appalachian Power Company, Columbus Southern Power Company, Indiana Michigan Power Company, Kentucky Power Company, and Ohio Power company, (the AEP Companies) tendered for filing an amendment to the AEP System Interim Allowance Agreement. The purpose of the amendment to the Agreement is to establish the allocation of costs and revenues related to the sale or purchase of allowances to or from non-affiliated companies.

The AEP Companies request an effective date of September 1, 1996, but the Amendment relates back to the effective date of the Agreement.

Copies have been served upon the state regulatory commissions in Indiana, Kentucky, Michigan, Ohio, Tennessee, Virginia and West Virginia.

Comment date: July 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

12. The Cleveland Electric Illuminating Company

[Docket No. ER96–2214–000]

Take notice that on June 24, 1996, The Cleveland Electric Illuminating Company (CEI), filed pursuant to § 205 of the Federal Power Act and Part 35 of the Commissions Regulations, thereunder electric power service agreements between CEI and Rainbow Energy Marketing Corporation, LG&E Power Marketing, Inc. and Central Illinois Public Service Company. CEI

requests an effective date of the agreements of June 24, 1996.

Comment date: July 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

13. Duke Power Company

[Docket No. ER96–2215–000]

Take notice that on June 24, 1996, Duke Power Company (Duke), tendered for filing an unexecuted Service Agreement for Market Rate (Schedule MR) Sales between Duke, on its own behalf and acting as agent for its wholly-owned subsidiary, Nantahala Power and Light Company, and Enron Power Marketing, Inc. and a Schedule MR Transaction Sheet thereunder.

Comment date: July 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

14. Louisville Gas and Electric Company

[Docket No. ER96–2216–000]

Take notice that on June 24, 1996, Louisville Gas and Electric Company (LG&E), tendered for filing a copy of a Non-Firm Transmission Agreement between Louisville Gas and Electric Company and Tennessee Valley Authority (TVA) under Rate TS.

Comment date: July 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

15. Kentucky Utilities Company

[Docket No. ER96–2217–000]

Take notice that on June 24, 1996, Kentucky Utilities Company (KU), tendered for filing a service agreement between KU and PECO Energy Company under its Power Services (PS) Tariff. KU requests an effective date of May 22, 1996.

Comment date: July 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

16. Kansas City Power & Light Company

[Docket No. ER96–2218–000]

Take notice that on June 24, 1996, Kansas City Power & Light Company (KCPL), tendered for filing Amendatory Agreement No. 3 to Municipal Agreement between KCPL and the City of Osawatomic, Kansas, dated June 19, 1996, and associated Service Schedule. KCPL states that the Amendatory Agreement revises the Agreement pursuant to KCPL's Open Season.

KCPL requests waiver of the Commission's notice requirements.

Comment date: July 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

17. Northern Indiana Public Service Company

[Docket No. ER96–2219–000]

Take notice that on June 25, 1996, Northern Indiana Public Service Company, tendered for filing an executed Service Agreement between Northern Indiana Public Service Company and Delhi Energy Services, Inc.

Under the Service Agreement, Northern Indiana Public Service Company agrees to provide services to Delhi Energy Services, Inc. under Northern Indiana Public Service Company's Power Sales Tariff, which was accepted for filing by the Commission and made effective by Order dated August 17, 1995 in Docket No. ER95–1222–000. Northern Indiana Public Service Company and Delhi Energy Services, Inc. request waiver of the Commission's sixty-day notice requirement to permit an effective date of July 1, 1996.

Copies of this filing have been sent to the Indiana Utility Regulatory Commission and the Indiana Office of Utility Consumer Counselor.

Comment date: July 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

18. Northern Indiana Public Service Company

[Docket No. ER96–2220–000]

Take notice that on June 25, 1996, Northern Indiana Public Service Company, tendered for filing an executed Service Agreement between Northern Indiana Public Service Company and Commonwealth Edison Company.

Under the Service Agreement, Northern Indiana Public Service Company agrees to provide services to Commonwealth Edison Company under Northern Indiana Public Service Company's Power Sales Tariff, which was accepted for filing by the Commission and made effective by Order dated August 17, 1995 in Docket No. ER95–1222–000. Northern Indiana Public Service Company and Commonwealth Edison Company request waiver of the Commission's sixty-day notice requirement to permit an effective date of July 1, 1996.

Copies of this filing have been sent to the Indiana Utility Regulatory Commission and the Indiana Office of Utility Consumer Counselor.

Comment date: July 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

19. Wisconsin Power and Light Company

[Docket No. ER96–2221–000]

Take notice that on June 24, 1996, Wisconsin Power and Light Company (WP&L), tendered for filing an Agreement dated June 14, 1996, establishing Eastex Power Marketing, Inc. as a customer under the terms of WP&L's Point-to-Point Transmission Tariff.

WP&L requests an effective date of June 14, 1996 and accordingly seeks waiver of the Commission's notice requirements. A copy of this filing has been served upon the Public Service Commission of Wisconsin.

Comment date: July 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

20. Pennsylvania Power & Light Co.

[Docket No. ER96–2222–000]

Take notice that on June 25, 1996, Pennsylvania Power & Light Company (PP&L), tendered for filing with the Federal Energy Regulatory Commission Service Agreements (the Agreements) between PP&L and DuPont Power Marketing, Inc., dated May 21, 1996, between PP&L and VASTAR Power Marketing, Inc., dated June 10, 1996, between PP&L and Delmarva Power & Light Company dated June 3, 1996, and between PP&L and AIG Trading Corporation dated June 18, 1996.

The Agreements supplement a Short Term Capacity and Energy Sales umbrella tariff approved by the Commission in Docket No. ER95–732–000 on June 21, 1995.

In accordance with the policy announced in *Prior Notice and Filing Requirements Under Part II of the Federal Power Act,* 64 FERC ¶ 61,139, *clarified and reh'g granted in part and denied in part,* 65 FERC ¶ 61,081 (1993), PP&L requests the Commission to make the Agreements effective as of June 24, 1996, because service will be provided under an umbrella tariff and each service agreement is filed within 30 days after the commencement of service. In accordance with 18 CFR 35.11, PP&L also requested waiver of certain filing requirements for information previously filed with the Commission in Docket No. ER95–732–000.

PP&L states that a copy of its filing was provided to the customers involved and to the Pennsylvania Public Utility Commission.

Comment date: July 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

21. Texas-New Mexico Power Company

[Docket No. ES96–35–000]

Take notice that on June 26, 1996, Texas-New Mexico Power Company (TNP) filed an application, under § 204 of the Federal Power Act, requesting that the Commission:

(1) authorize TNP to enter into a secured bank syndicated credit agreement in an amount up to $100 million and to issue up to $100 million of New Bonds to secure the credit agreement; and

(2) grant any other authority that the Commission deems necessary to authorize TNP to participate in the proposed transaction.

Comment date: July 17, 1996, in accordance with Standard Paragraph E at the end of this notice.

22. Old Dominion Electric Cooperative

[Docket No. ES96–36–000]

Take notice that on June 27, 1996, Old Dominion Electric Cooperative (ODEC) filed an application, under § 204 of the Federal Power Act, seeking authorization to issue up to and including $110 million of zero coupon First Mortgage Bonds which will be used to secure ODEC's obligations under the equity security deposit provisions of its lease/lease-back of the Clover Power Station Unit 1 which was authorized by the Commission in Docket No. ES96–1–000.[1]

Comment date: July 26, 1996, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraph

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, 888 First 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. 96–17343 Filed 7–8–96; 8:45 am]

BILLING CODE 6717–01–P

[1] 73 FERC § 62,120 (1995).

[Docket No. CP96–201–000]

Algonquin Gas Transmission Company; Notice of Availability of the Environmental Assessment for the Proposed Middletown Lateral Project

July 2, 1996.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared an environmental assessment (EA) on the natural gas pipeline facilities proposed by Algonquin Gas Transmission Company (Algonquin) in the above-referenced docket.

The EA was prepared to satisfy the requirements of the National Environmental Policy Act. The staff concludes that approval of the proposed project, with appropriate mitigating measures, would not constitute a major Federal action significantly affecting the quality of the human environment.

The EA assesses the potential environmental effects of the construction and operation of the proposed pipeline facilities including:

- 8.4 miles of 20-inch-diameter pipeline (the Middletown Lateral) from Algonquin's existing mainline system in Glastonbury, Hartford County, Connecticut to The Connecticut Light and Power Company's (CL&P) electric generating station in Middletown, Middlesex County, Connecticut (Middletown Plant);
- A meter station; and.
- A tap value site and appurtenant facilities.

CL&P would construct nonjurisdictional facilities consisting of approximately 1,500 feet of piping, a regulator station, and burner conversion equipment. All of CL&P's facilities would be constructed within its plant site.

The purpose of the proposed facilities would be to provide up to 82,500 million British thermal units of gas per day to CL&P for use as an alternate fuel for Unit Nos. 2 and 3 at its Middletown Plant.

The EA has been placed in the public files of the FERC and is available for public inspection at: Federal Energy Regulatory Commission, Public Reference and Files Maintenance Branch, 888 First Street, N.E., Washington, DC 20426, (202) 208–1371.

Copies of the EA have been mailed to Federal, state and local agencies, public interest groups, interested individuals, newspapers, and parties to this proceeding.

A limited number of copies of the EA are available from: Mr. John Wisniewski, Environmental Project Manager, Environmental Review and Compliance Branch II, Office of Pipeline Regulation, PR–11.2, 888 First Street, N.E., Washington, DC 20426, (202) 208–0896.

Any person wishing to comment on the EA may do so. Written comments must reference Docket No. CP96–201–000, and be addressed to: Office of the Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426.

Comments should be filed as soon as possible, but must be received no later than August 1, 1996, to ensure consideration prior to a Commission decision on this proposal. A copy of any comments should also be sent to Mr. John Wisniewski, Environmental Project Manager, PR–11.2, at the above address.

Comments will be considered by the Commission but will not serve to make the commentor a party to the proceeding. Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.214).

The date for filing timely motions to intervene in this proceeding has passed. Therefore, parties now seeking to file later interventions must show good cause, as required by section 385.214(b)(3), why this time limitation should be waived. Environmental issues have been viewed as good cause for late intervention. You do not need intervenor status to have your comments considered.

Additional information about this project is available from Mr. John Wisniewski, Environmental Project Manager.

Lois D. Cashell,

Secretary.

[FR Doc. 96–17407 Filed 7–8–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP96–517–000]

Algonquin LNG, Inc.; Notice of Public Scoping Meeting and Site Inspection, Algonquin LNG Modifications Project

July 2, 1996.

On July 15, 1996, at 7:00 p.m., the Office of Pipeline Regulation environmental staff will conduct a public scoping meeting for the facilities proposed in the Algonquin LNG Modification's Project in Providence, Rhode Island. The meeting will be held at the Rhode Island Public Utilities Commission, Third Floor Hearing Room, 100 Orange Street, Providence, Rhode Island.

The public meeting will be designed to give more detailed information and

another opportunity to offer comments on the proposed project. Those wanting to speak at the meeting can call the Environmental Assessment (EA) Project Manager to preregister their names on the speaker list. Individuals on the speaker list before the date of the meeting will be allowed to speak first. A second speaker list will be developed at the meeting. Priority will be given to people representing groups. A transcript of each meeting will be made so that your comments will be accurately recorded.

In addition to the public meeting, the environmental staff will inspect the proposed project sites on the afternoon of July 15, 1996. Those planning to attend must provide their own transportation. For further information, call Chris Zerby, EA Project Manager, at (202) 208–0111.

Kevin P. Madden,

Director, Office of Pipeline Regulation.

[FR Doc. 96–17408 Filed 7–8–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP96–477–000]

K N Interstate Gas Transmission Company; Notice of Intent To Prepare an Environmental Assessment for the Proposed Pony Express Pipeline Project and Request for Comments on Environmental Issues

July 2, 1996.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the construction and operation of the facilities proposed in the Pony Express Pipeline Project.[1] This EA will be used by the Commission in its decision-making process to determine whether an environmental impact statement is necessary and whether to approve the project.

Summary of the Proposed Project

K N Interstate Gas Transmission Company (KN) proposes to convert an existing crude oil pipeline owned by Amoco Pipeline Company (Amoco) to natural gas service. The oil pipeline crosses portions of five states and extends between Lost Cabin, Wyoming and Freeman, Missouri. Together with several smaller components, the project would have the capacity to transport natural gas with an energy content of up to 255 billion Btus per day from the Wind River Basin in central Wyoming and major gas producing areas of southwest Wyoming. It will also interconnect with or cross a number of other interstate gas transportation systems, including KN's existing system (8 locations), ANR Pipeline Company, Natural Gas Pipeline Company of America, Northern Natural Gas Company, Panhandle Eastern Pipeline Company, Trailblazer Pipeline Company, and Williams Natural Gas Company.

The proposed project would include the following components:

- Conversion of the 914-mile-long Amoco oil pipeline to natural gas service (of which an 804-mile-long segment would be acquired by KN);
- Construction of approximately 65 miles of 16-inch-diameter pipeline between Rockport (Weld County), Colorado and an interconnection with the converted Amoco pipeline near Kimball (Kimball County), Nebraska;
- Construction of approximately 7.6 miles of 12-inch-diameter pipeline to reroute the converted Amoco pipeline around a portion of Casper, Wyoming;
- Construction of approximately 0.3 mile of 24-inch-diameter pipeline to reroute the converted Amoco pipeline around a congested area near Appanoose School (Franklin County), Kansas;
- Construction of approximately 1.6 miles of 20-inch-diameter inlet and 1.6 miles of 20-inch-diameter outlet pipeline between the converted Amoco pipeline and KN's existing Casper Compressor Station (Natrona County), Wyoming;
- Construction/installation of 50,500 horsepower of compression at five compressor stations;
- Upgrade 58 miles of existing 12-inch-diameter pipeline extending from the Huntsman Compressor Station (Cheyenne County), Nebraska to the Weld County, Colorado interconnect;
- Construction of two interconnects in Natrona County, Wyoming consisting of two 2,000-foot-long sections of 12-inch-diameter pipeline; and construction of one interconnect in Madden, Wyoming consisting of 0.1 mile of 10-inch-diameter; and
- Upgrade 0.2 mile of 20-inch-diameter pipeline in Platt County, Wyoming.
- In addition, about 114 miles of 12-inch-diameter oil pipeline would be constructed for Amoco between Amoco's storage facilities in Casper, Wyoming to an interconnect with the existing Amoco pipeline system at Fort Laramie, Wyoming. This oil pipeline would be constructed by KN Energy, KN Interstate's non-jurisdictional parent company.

The general location of the project facilities and specific locations for facilities on new sites are shown in appendix 1.[2]

Land Requirements for Construction

Construction of the proposed facilities would require about 717 acres of land. Following construction, about 108 acres would be maintained as new aboveground facility sites and new permanent right-of-way. The remaining 609 acres of land would be restored and allowed to revert to its former use.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us to discover and address concerns the public may have about proposals. We call this '''scoping.'' The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this Notice of Intent, the Commission requests public comments on the scope of the issues it will address in the EA. All comments received are considered during the preparation of the EA. State and local government representatives are encouraged to notify their constituents of this proposed action and encourage them to comment on their areas of concern.

The EA will discuss impacts that could occur as a result of the construction and operation of the proposed project under these general headings:

- geology and soils
- water resources, fisheries, and wetlands
- vegetation and wildlife
- endangered and threatened species
- public safety
- land use
- cultural resources
- air quality and noise
- hazardous waste

We will also evaluate possible alternatives to the proposed project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

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[1] K N Interstate Gas Transmission Company's application was filed with the Commission under Section 7 of the Natural Gas Act and Part 157 of the Commission's regulations.

[2] The appendices referenced in this notice are not being printed in the Federal Register. Copies are available from the Commission's Public Reference and Files Maintenance Branch, 888 First Street NE., Washington, DC 20426, or call (202) 208–1371. Copies of the appendices were sent to all those receiving this notice in the mail.

Our independent analysis of the issues will be in the EA. Depending on the comments received during the scoping process, the EA may be published and mailed to Federal, state, and local agencies, public interest groups, interested individuals, affected landowners, newspapers, libraries, and the Commission's official service list for this proceeding. A comment period will be allotted for review if the EA is published. We will consider all comments on the EA before we recommend that the Commission approve or not approve the project.

Currently Identified Environmental Issues

We have already identified several issues that we think deserve attention based on a preliminary review of the proposed facilities and the environmental information provided by KN. This preliminary list of issues may be changed based on your comments and our analysis.

- Nine federally listed endangered and threatened species and two candidate species may be present in the project area.
- Four perennial waterbodies would be crossed by the proposed facilities, including the North Platte River in Wyoming.
- The site of the proposed North Platte River crossing is adjacent to the Brookhurst Superfund site near Casper, Wyoming.

Also, we have made a preliminary decision to not address the impacts of the nonjurisdictional KN Energy facilities discussed on page 2. We will briefly describe their location and status in the EA.

Public Participation

You can make a difference by sending a letter addressing your specific comments or concerns about the project. You should focus on the potential environmental effects of the proposal, alternatives to the proposal including alternative routes), and measures to avoid or lessen environmental impact. The more specific your comments, the more useful they will be. Please follow the instructions below to ensure that your comments are received and properly recorded:

- Address your letter to: Lois Cashell, Secretary, Federal Energy Regulatory Commission, 888 First St., N.E., Washington, DC 20426;
- Reference Docket No. CP96–477–000;
- Send a *copy* of your letter to: Ms. Elizabeth J. Secrest, EA Project Manager, Federal Energy Regulatory Commission, 888 First St., NE., PR–11.1, Washington, DC 20426; and
- Mail your comments so that they will be received in Washington, DC, on or before August 1, 1996.

If you wish to receive a copy of the EA, you should request one from Ms. Secrest at the above address.

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an official party to the proceeding or become an ''intervenor.'' Among other things, intervenors have the right to receive copies of case-related Commission documents and filings by other intervenors. Likewise, each intervenor must provide copies of its filings to all other parties. If you want to become an intervenor you must file a motion to intervene according to Rule 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.214) (see appendix 2).

The date for filing timely motions to intervene in this proceeding has passed. Therefore, parties now seeking to file late interventions must show good cause, as required by section 385.214(b)(3), why this time limitation should be waived. Environmental issues have been viewed as good cause for late intervention. You do not need intervenor status to have your scoping comments considered.

Additional information about the proposed project is available from Ms. Elizabeth J. Secrest, EA Project Manager, at (202) 208–0918.

Lois D. Cashell,

Secretary.

[FR Doc. 96–17344 Filed 7–8–96; 8:45 am]

BILLING CODE 6717–01–M

[Project No. 2482–021]

Niagara Mohawk Power Corporation; Notice of Availability of Final Environmental Assessment

July 2, 1996.

A final environmental assessment (FEA) is available for public review. The FEA was prepared for an application filed by Niagara Mohawk Power Corporation (licensee) to remove polychlorinated biphenyls (PCBs) from lands within the boundary of the Hudson River Hydroelectric Project. The licensee proposes to remove PCBs at the Queensbury site in accordance with a record of decision issued March 1995 by the New York State Department of Environmental Conservation. In summary, the licensee proposes to excavate and remove all surface soil (1 foot from surface) on the upland portion of the site with total PCB concentrations in excess of 1 ppm and subsurface soil with concentrations in excess of 10 ppm. Further, the licensee proposes to excavate and remove to a depth of 2 feet near-shore river sediments. The Queensbury site is located on Corinth Road, Town of Queensbury, Warren County, New York, on the north bank of the Hudson River, about 5 miles west of Glens Falls, New York.

The FEA finds that the licensee's remediation plan is not a major federal action significantly affecting the quality of the human environment. The FEA was written by staff in the Office of Hydropower Licensing, Federal Energy Regulatory Commission. Copies of the FEA can be obtained by calling the Commission's Public Reference Room at (202) 208–1371.

Lois D. Cashell,

Secretary.

[FR Doc. 96–17409 Filed 7–8–96; 8:45 am]

BILLING CODE 6717–01–M

Hydroelectric Applications [Idaho Power Company, et al.]; Notice of Applications

[Project Nos. 1975–014, et al.]

Take notice that the following hydroelectric applications have been filed with the Commission and are available for public inspection:

1a. *Type of Application:* Major New License.

b. *Project No.:* 1975–014.

c. *Date filed:* December 20, 1995.

d. *Applicant:* Idaho Power Company.

e. *Name of Project:* Bliss.

f. *Location:* On the Snake River, at river mile 560 from the confluence with the Columbia River in Gooding, Twin Falls, and Elmore Counties, Idaho.

g. *Filed Pursuant to:* Federal Power Act, 16 USC §§ 791(a)–825(r).

h. *Applicant Contact:* Robert W. Stahman, Idaho Power Company, 1221 West Idaho Street, P.O. Box 70, Boise, ID 83707, (208) 388–2676.

i. *FERC Contact:* Héctor M. Pérez, (202) 219–2843.

j. *Deadline for filing interventions and protests:* August 29, 1996.

k. *Status of Environmental Analysis:* This application is not ready for environmental analysis at this time—see attached paragraph E.

l. *Brief Description of Project:* The project consists of: (1) an 84-foot-high, 364-foot-long concrete dam with a crest elevation of 2,655 feet mean sea level (msl); (2) a 216-foot-long concrete ogee spillway with a crest elevation of 2,624 feet and four bays equipped with 30-foot-high tainter gates; (3) Bliss

Reservoir with a normal maximum surface area of 255 acres at a normal maximum water surface elevation of 2,654 feet msl; (4) four intakes and four 22-foot-diameter penstocks included as an integral part of the dam; (5) a concrete powerhouse at the base of the dam containing three turbine-generator units with a total installed capacity of 75,000 kilowatts and a skeleton bay for installation of a fourth unit; (6) a 10.5-mile-long, 138-kilovolt transmission line; and (7) other appurtenances.

m. *This notice also consists of the following standard paragraph:* B1, and E.

n. Requests for additional studies have been filed in accordance with section 4.32(b)(7) of the Commission's regulations. These study requests will be addressed in the additional information request to be issued later in the licensing proceeding.

2a. *Type of Application:* Major New License.

b. *Project No.:* 2061–004.

c. *Date filed:* December 20, 1995.

d. *Applicant:* Idaho Power Company.

e. *Name of Project:* Lower Salmon Falls.

f. *Location:* On the Snake River, at river mile 573 from the confluence with the Columbia River in Gooding and Twin Falls Counties, Idaho.

g. *Filed Pursuant to:* Federal Power Act, 16 USC §§ 791(a)–825(r).

h. *Applicant Contact:* Robert W. Stahman, Idaho Power Company, 1221 West Idaho Street, P.O. Box 70, Boise, ID 83707, (208) 388–2676.

i. *FERC Contact:* Héctor M. Pérez, (202) 219–2843.

j. *Deadline for filing interventions and protests:* August 29, 1996.

k. *Status of Environmental Analysis:* This application is not ready for environmental analysis at this time—see attached paragraph E.

l. *Brief Description of Project:* The project consists of: (1) the Lower Falls Reservoir with a surface area of 750 acres at a normal maximum surface elevation of 2,798 feet; (2) a concrete dam with a 314-foot-long powerhouse at the right bank with four generating units with a total installed capacity of 60,000 kilowatts, a 97-foot-long bulkhead with 22-foot-diameter penstock (sealed) and a fishladder intake, a 312-foot-long spillway with eight bays equipped with 14.5-foot-high steel tainter gates, a 180-foot-long overflow section, and an 80-foot-long left abutment; (3) two 138-kilovolt short transmission lines; and (4) other appurtenances.

m. *This notice also consists of the following standard paragraph:* B1, and E.

n. Requests for additional studies have been filed in accordance with section 4.32(b)(7) of the Commission's regulations. These study requests will be addressed in the additional information request to be issued later in the licensing proceeding.

3a. *Type of Application:* Major New License.

b. *Project No.:* 2777–007.

c. *Date filed:* December 20, 1995.

d. *Applicant:* Idaho Power Company.

e. *Name of Project:* Upper Salmon Falls.

f. *Location:* On the Snake River, at river mile 580 from the confluence with the Columbia River in Gooding and Twin Falls Counties, Idaho.

g. *Filed Pursuant to:* Federal Power Act, 16 USC §§ 791(a)–825(r).

h. *Applicant Contact:* Robert W. Stahman, Idaho Power Company, 1221 West Idaho Street, P.O. Box 70, Boise, ID 83707, (208) 388–2676.

i. *FERC Contact: Héctor M. Pérez, (202) 219–2843.*

j. *Deadline for filing interventions and protests:* August 29, 1996.

k. *Status of Environmental Analysis:* This application is not ready for environmental analysis at this time—see attached paragraph E.

l. *Brief Description of Project:* The project consists of: (1) the 1,620-foot-long concrete Upper Salmon Falls Dam comprised of a 240-foot-long gated spillway section adjacent to the north (right) abutment with a crest elevation of 2,865.4 feet mean sea level (msl), a 610-foot-long section with flashboards with a crest elevation of 2,876.4 feet msl, a 275-foot-long intake structure adjacent to the south abutment (to feed the power canal for Plant B) and 420 feet of left and right abutment gravity sections with crest elevations of 2,889.5 feet; (2) the Upper Salmon Falls Reservoir with a normal maximum elevation of 2,878.2 feet; (3) a 3,200-foot-long concrete-lined canal conducting water to Plant B; (4) a powerhouse (Plant B) with an installed capacity of 16,560 kilowatts; (5) a tailrace that forms the upstream part of the approximately 1,580-foot-long power canal to Plant A; (6) Plant A with an installed capacity of 18,000 kilowatts; and (7) other appurtenances.

m. *This notice also consists of the following standard paragraph:* B1, and E.

n. Requests for additional studies have been filed in accordance with section 4.32(b)(7) of the Commission's regulations. These study requests will be addressed in the additional information request to be issued later in the licensing proceeding.

4a. *Type of Application:* Minor New License.

b. *Project No.:* 1994–004.

c. *Date filed:* November 2, 1995.

d. *Applicant:* Heber Light and Power Company.

e. *Name of Project:* Snake Creek.

f. *Location:* Partially within Uintah National Forest, on Snake Creek, in Wasatch County, Utah.

g. *Filed Pursuant to:* Federal Power Act, 16 USC §§ 791(a)–825(r).

h. *Applicant Contact:* Mr. Alden C. Robinson, Sunrise Engineering, Inc., 25 East 500 North, P.O. Box 186, Fillmore, UT 84631, (801) 743–6151.

i. *FERC Contact:* Michael Spencer at (202) 219–2846.

j. *Deadline Date for Protests and Interventions: September 6, 1996.*

k. *Status of Environmental Analysis:* This application is not ready for environmental analysis at this time—see attached paragraph E1.

l. *Brief Description of Project:* The exiting project consists of: (1) a grated penstock inlet; (2) a 16,417-foot-long, 16-inch-diameter penstock; (3) a powerhouse containing one generating unit with a capacity of 800 kW and an average annual generation of 4.3 GWh; and (4) a 12.4 kV transmission line.

m. *Purpose of Project:* All project energy generated is utilized by the licensee.

n. *This notice also consists of the following standard paragraphs:* B1, and E1.

5a. *Type of Application:* Major License.

b. *Project No.:* 11175–002.

c. *Date filed:* January 3, 1995.

d. *Applicant:* Crown Hydro Company.

e. *Name of Project:* Crown Mill.

f. *Location:* On the Mississippi River, in the City of Minneapolis, Hennepin County, Minnesota.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. §§ 791(a)–825(r).

h. *Applicant Contact:* Mr. Thomas R. Griffin, Crown Hydro Company, 5436 Columbus Avenue South, Minneapolis, MN 55417, (612) 825–1043.

i. *FERC Contact:* Charles T. Raabe (202) 219–2811.

j. *Deadline Date:* September 2, 1996.

k. *Status of Environmental Analysis:* This application is ready for environmental analysis at this time—see attached paragraph D9.

l. *Description of Project:* The proposed project would utilize the existing U.S. Army Corps of Engineers' Upper St. Anthony Falls dam and reservoir and would consist of: (1) a reconstructed upper canal and intake tunnel; (2) a proposed powerhouse room, to be constructed on the lower level of Crown

Mill, containing two hydropower units with a total capacity of 3,400-kW; (3) an existing tailrace tunnel and a reconstructed tailrace canal; (4) a proposed underground transmission line; and (5) appurtenant facilities.

The estimated annual energy production would be 16,650 MWh. Project power would be sold to Northern States Power Company.

m. *This notice also consists of the following standard paragraphs:* A4 and D9.

n. *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 Crown Hydro Company, 5436 Columbus Avenue South, Minneapolis, MN 55417.

6a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 11578–000.

c. *Date filed:* April 24, 1996.

d. *Applicant:* Powerwheel Corporation.

e. *Name of Project:* Oroville Fish Barrier Dam.

f. *Location:* At Oroville Fish Barrier Dam, on the Feather River, near the town of Oroville, in Butte County, California.

g. *Filed Pursuant to:* Federal Power Act 16 USC §§ 791(a)–825(r).

h. *Applicant Contact:* Mr. Kenneth R. Broome, 100 Rocky Creek Road, Woodside, CA 94062, (915) 529–1810.

i. *FERC Contact:* Michael Spencer at (202) 219–2846.

j. *Comment Date:* September 6, 1996.

k. *Description of Project:* The proposed project would utilize the State of California's Oroville Fish Barrier Dam and consist of: (1) the existing 91-foot-high concrete gravity dam; (2) the reservoir, which has a surface area of 25 acres and 250 acre-feet of storage capacity; (3) a proposed powerhouse containing one generating unit with a capacity of 436 kW and an average annual generation of 3.4 GWh; and (4) a 1,000-foot-long underground transmission line.

No new access road will be needed to conduct the studies. The applicant estimates that the cost of the studies to be conducted under the preliminary permit would be $15,000.

l. *Purpose of Project:* Project power would be sold.

m. *This notice also consists of the following standard paragraphs:* A5, A7, A9, A10, B, C, and D2.

7a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 11581–000.

c. *Date Filed:* June 12, 1996.

d. *Applicant:* Augusta-Richmond County, Georgia.

e. *Name of Project:* Augusta Canal Water Power Project.

f. *Location:* On the Savannah River, Augusta-Richmond County, Georgia.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. §§ 791(a)–825(r).

h. *Applicant Contact:* Mr. Charles T. Dillard, 803 Municipal Building, Augusta, GA 30911, (404) 821–1714.

i. *FERC Contact:* Michael Dees (202) 219–2807.

j. *Comment Date:* September 2, 1996.

k. *Competing Application:* Project No. 11490–000; Date Filed: July 11, 1994; Competition Due Date: May 17, 1996.

l. *Description of Project:* The applicant proposes to study three different configurations for the proposed hydropower facility. The proposed project would consist of: (1) the existing stone-masonry Augusta Diversion dam, which is approximately 1,600 feet long; (2) the existing Augusta Diversion Dam impoundment; (3) the existing Augusta Canal; (4) a proposed intake structure; (5) a proposed powerhouse located at one of three possible sites, containing from two to four hydropower units with a total capacity ranging from 5,600 kW to 12,000 kW; (6) a proposed tailrace structure; (7) a proposed transmission line from the powerhouse to the municipal raw water pumping station; and (8) appurtenant facilities. The applicant estimates that the annual energy generation would range from 23,000 MWh to 65,000 MWh and that the cost of the studies to be performed under the permit would be $315,000. Project energy would be used by the applicant to operate its raw water pumping station. The dam and canal are owned by the applicant.

m. *This notice also consists of the following standard paragraphs:* A8, A10, B, C, and D2.

8a. *Type of Application:* Petition for Declaratory Order.

b. *Docket No:* DI96–7–000.

c. *Date Filed:* 06/03/96.

d. *Applicant:* Pacificorp.

e. *Name of Project:* Powerdale Hydroelectric Project.

f. *Location:* On the Hood River in Hood River County, Oregon.

g. *Filed Pursuant to:* Section 23(b) of the Federal Power Act, 16 U.S.C. §§ 817(b).

h. *Applicant Contact:* S. A. deSousa, Director Hydro Resources, 920 S.W. Sixth Avenue, Portland, OR 97204–1256, (503) 464–5000.

i. *FERC Contact:* Diane M. Murray, (202) 219–2682.

j. *Comment Date:* August 9, 1996.

k. *Description of Project:* (1) a reservoir with a surface area of about 5 acres and a gross storage capacity of about 10 acre-feet; a 10-foot-high, 206-feet-long concrete diversion dam; (2) a 604-foot-long power canal; (3) a 980-foot-long wood flume; (4) a 14,354-foot-long pipeline; (5) a powerhouse with a 6,000 kW generating unit; (6) and appurtenant facilities.

When a Petition for Declaratory Order is filed with the Federal Energy Regulatory Commission, the Federal Power Act requires the Commission to investigate and determine if the interests of interstate or foreign commerce would be affected by the project. The Commission also determines whether or not the project: (1) would be located on a navigable waterway; (2) would occupy or affect public lands or reservations of the United States; (3) would utilize surplus water or water power from a government dam; or (4) if applicable, has involved or would involve any construction subsequent to 1935 that may have increased or would increase the project's head or generating capacity, or have otherwise significantly modified the project's pre-1935 design or operation.

l. *Purpose of Project:* To produce power.

m. *This notice also consists of the following standard paragraphs:* B, C1, and D2.

9a. *Type of Application:* Amendment of exemption.

b. *Project No:* 5637–003.

c. *Date Filed:* April 22, 1996.

d. *Applicant:* Pancheri, Inc.

e. *Name of Project:* Pancheri Project.

f. *Location:* Butte County, Howe, Idaho.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Jerry Pancheri, HC 65 Box 2104, Howe, Idaho 83244, (208) 767–3419.

i. *FERC Contact:* Susan Tseng, (202) 219–2798.

j. *Comment Date:* August 9, 1996.

k. *Description of Project:* Sorenson Engineering, P.A., on behalf of the exemptee, Pancheri, Inc., has filed an application to amend project features for the Pancheri Project. The exemptee currently has a 300-foot long, 10-inch diameter pipe connection with the Telford Irrigation Pipeline. The exemptee proposes to repair deteriorated portions of the Telford Pipeline by replacing 172 feet of the 10-inch diameter steel pipe with a 20-inch

diameter steel pipe, and also portions of the associated ditches. The exemptee also proposes to construct a new powerhouse to be located within approximately 30 feet from the existing powerhouse. Construction of a new powerhouse would require approximately 30 feet of new 12.2 KVA line to be connected to the existing 12.2 KVA transmission system.

l. *This notice also consists of the following standard paragraphs:* B, C1, and D2.

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) 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) and 4.36.

A8. Preliminary Permit—Public notice of the filing of the initial preliminary permit application, which has already been given, established the due date for filing competing preliminary permit applications or notices of intent. Any competing preliminary permit or development application or notice of intent to file a competing preliminary permit or development application must be filed in response to and in compliance with the public notice of the initial preliminary permit application. No competing applications or notices of intent to file competing applications may be filed in response to this notice. A competing license application must conform with 18 CFR 4.30(b) 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 would 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.

B1. Protests or Motions to Intervene—Anyone may submit a protest or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests 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 protests or motions to intervene must be received on or before the specified deadline 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, 888 First Street, N.E., Washington, D.C. 20426. An additional copy must be sent to Director, Division of Project Review, Federal Energy Regulatory Commission, 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, 888 First Street, N.E., Washington, D.C. 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 comments 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 26, 1996 for Project No. 11175–002). All reply comments must be filed with the Commission within 105 days from the date of this notice (October 8, 1996 for Project No. 11175–002).

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, 888 First Street, N.E., Washington, D.C. 20426. An additional copy must be sent to Director, Division of Project Review, Office of Hydropower Licensing, Federal Energy Regulatory Commission, 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.

E. Filing and Service of Responsive Documents—The application is not ready for environmental analysis at this time; therefore, the Commission is not now requesting comments, recommendations, terms and conditions, or prescriptions.

When the application is ready for environmental analysis, the Commission will notify all persons on the service list and affected resource agencies and Indian tribes. If any person wishes to be placed on the service list, a motion to intervene must be filed by the specified deadline date herein for such motions. All resource agencies and Indian tribes that have official responsibilities that may be affected by the issues addressed in this proceeding, and persons on the service list will be able to file comments, terms and conditions, and prescriptions within 60 days of the date the Commission issues a notification letter that the application is ready for an environmental analysis. All reply comments must be filed with the Commission within 105 days from the date of that letter.

All filings must (1) bear in all capital letters the title ''PROTEST'' or ''MOTION TO INTERVENE;'' (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 protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. 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, 888 First Street, N.E., Washington, D.C. 20426. An additional copy must be sent to Director, Division of Project Review, Office of Hydropower Licensing, Federal Energy Regulatory Commission, at the above address. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application.

E1. Filing and Service of Responsive Documents—The application is not ready for environmental analysis at this time; therefore, the Commission is not now requesting comments, recommendations, terms and conditions, or prescriptions.

When the application is ready for environmental analysis, the Commission will issue a public notice requesting comments, recommendations, terms and conditions, or prescriptions.

All filings must (1) bear in all capital letters the title ''PROTEST'' or ''MOTION TO INTERVENE;'' (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 protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. Agencies may obtain copies of the application directly from the applicant. 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, 888 First Street, N.E., Washington, D.C. 20426. An additional copy must be sent to Director, Division of Project Review, Office of Hydropower Licensing, Federal Energy Regulatory Commission, at the above address. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application.

Dated: June 28, 1996, Washington, DC.

Lois D. Cashell,

Secretary.

[FR Doc. 96–17345 Filed 7–8–96; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5530–6]

Notice of Proposed Prospective Purchaser Agreement Pursuant to the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as Amended by the Superfund Amendments and Reauthorization Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice: Request for public comment.

SUMMARY: Notice is hereby given that a proposed prospective purchaser agreement associated with the Upper Animas Mining District Site, at the Mayflower Mill property (the ''Mill'') located near Silverton, in San Juan County, Colorado, was executed by the Agency on May 6, 1996 and executed by the United States Department of Justice on June 18, 1996. This agreement is subject to final approval after the comment period. The Prospective Purchaser Agreement would resolve certain potential EPA claims under Sections 107 and 106 of the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended by the Superfund Amendments and Reauthorization Act of 1986 (''CERCLA''), against the non-profit San Juan County Historical Society, Inc., the prospective purchaser (''the Society''). The settlement would require the Society to clean the Mill, to use the Mill in a manner consistent with the goals of the Society, as stated in the Agreement, and to provide EPA access to the Mill.

For thirty (30) days following the date of publication of this notice, the Agency will receive written comments relating to the proposed settlement. The Agency's response to any comments

received will be available for public inspection at the U.S. Environmental Protection Agency, Region VIII, 999 18th Street, Suite 500, Denver, CO 80202.

DATES: Comments must be submitted on or before August 8, 1996.

AVAILABILITY: The proposed agreement is available for public inspection at the U.S. Environmental Protection Agency, Region VIII, 999 18th Street, Suite 500, Denver, CO 80202. A copy of the proposed agreement may be obtained from Richard L. Sisk (8ENF–L), Compliance Attorney, U.S. Environmental Protection Agency, Region VIII, 999 18th Street, Suite 500, Denver, CO 80202, (303) 312–6638. Comments should reference the ''San Juan County Historical Society Prospective Purchaser Agreement'' and should be forwarded to Richard L. Sisk at the above address.

FOR FURTHER INFORMATION CONTACT: Richard L. Sisk (8ENF–L), Compliance Attorney, U.S. Environmental Protection Agency, Region VIII, 999 18th Street, Suite 500, Denver, CO 80202, (303) 312–6638.

Dated: June 24, 1996.

Jack W. McGraw,

Acting Regional Administrator.

[FR Doc. 96–17320 Filed 7–8–96; 8:45 am]

BILLING CODE 6560–50–P

[FRL–5533–6]

Proposed Settlement Under Section 122(g) of the Comprehensive Environmental Response, Compensation and Liability Act; Tulalip Landfill Superfund Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed administrative settlement and opportunity for public comment.

SUMMARY: The U.S. Environmental Protection Agency (''EPA'') is proposing to enter into an administrative settlement to resolve claims under the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended (''CERCLA''). Notice is being published to inform the public of the proposed settlement and of the opportunity to comment. The settlement is intended to resolve past and estimated future liabilities of 187 *de minimis* parties for costs incurred, or to be incurred, by EPA at the Tulalip Landfill Superfund Site in Marysville, Washington.

DATES: Comments must be provided on or before August 8, 1996.

ADDRESSES: Comments should be addressed to Docket Clerk, U.S. Environmental Protection Agency, Region 10, ORC–158, 1200 Sixth Avenue, Seattle, Washington 98101, and should refer to In Re Tulalip Landfill Superfund Site, Marysville, Washington, U.S. EPA Docket No. 1093–08–01–104/122.

FOR FURTHER INFORMATION CONTACT: Cindy Colgate, Office of Environmental Cleanup (ECL–113), 1200 Sixth Avenue, Seattle, Washington 98101, (206) 553–1815.

SUPPLEMENTARY INFORMATION: In accordance with Section 122(i)(1) of CERCLA, notice is hereby given of a proposed administrative settlement concerning the Tulalip Landfill hazardous waste site located on Ebey Island between Steamboat Slough and Ebey Slough in the Snohomish River delta system between Everett and Marysville, Washington. The Site was listed on the National Priorities List (''NPL'') on April 25, 1995. 60 FR 20350 (April 25, 1995). Subject to review by the public pursuant to this Notice, the agreement has been approved by the United States Department of Justice. Below are listed the 184 parties who have executed the proposed Administrative Order on Consent.

Ace Galvanizing; Alaskan Copper & Brass; Albertson Food Center/ Albertson's Inc.; All City Fence Company/All City Fence Co., Inc.; American Building Maintenance (ABM); American Can Company/MCR Holdings, Inc.; American President Lines/ American Mail Line; Arden Farms Co./ Arden-Mayfair, Inc.; Art's Food Center; Auto Warehousing; Baugh Construction Co.; Bayless Bindery, Inc.; Bayley Construction/ Robert E. Bayley Construction, Inc.; Bethlehem Steel ; Boise Cascade Office Supply/Boise Cascade Office Products; Bon Marche/ The Bon, Inc./Federated Department Stores, Inc.; Brandrud Manufacturing; Broadmoor Golf Club; Buffalo Sanitary Wipers/Buffalo Industries, Inc.; Burlington Northern Railroad/ Burlington Northern, Inc.; Canteen Service, Inc.; Capital Industries, Inc.; Cases Inc./Flight Form Cases Inc.; Champion Bldg. Products/St. Regis/ Champion International Corporation; Chemithon Corp.; Children's Orthopedic Hospital/Children's Hospital and Medical Center; City of Kirkland; City of Seattle; Commercial Warehouse; Consolidated Freightways/ Consolidated Freightways Corporation of Delaware; Contour Laminates, Inc./ Radeke Corporation; Craftsman Press, Inc.; Cree Construction; Crosby & Overton; Crow Roofing; CX Processing/ Gretag Imaging, Inc.; Darigold, Inc.; David A. Mowat Co.; Deeny Construction Co., Inc.; E & E Meats; Eagle Metals Co./Alcan Aluminum Corporation; Ellstrom Manufacturing; Everett Community College; Everett Herald; Fabricators Inc./Furon Company; Fentron Industries/Fentron Building Products, Inc.; Firestone Store; Fisher Flour Mills/Fisher Mills Inc.; Fishermen's Boat Shop, Inc.; Ford Motor Company; Foss Maritime Company; Foster & Kleiser/Ackerley Communications, Inc.; Fred Meyer; Gall & Landau Construction/Gall Landau Young Construction Co., Inc. ; General Construction/Fletcher General, Inc.; General-Haskell-Amelco/Fletcher General, Inc./Haskell Corporation/ Amelco Industries; General Hospital/ Providence General Medical Center; General Services Administration; General Telephone (GTE)/GTE Northwest Inc.; Gordon Brown, Inc.; Group Health; Haight Roofing; Hardwood's Inc.; Henry Bacon Building Materials/CCD Enterprises; Hensel Phelps Construction; Herr Lumber Inc.; Hillis Homes, Inc./Centex Real Estate Corporation; Honeywell Inc./Alliant Techsystems Inc.; Howard S. Wright Construction/Fletcher Wright, Inc.; Hurlen Construction; Hussmann Corporation; Impression NW/K/P Corporation; Independent Paper/ Jefferson Smurfit Recycling Company; Industrial Transfer; Ivar's, Inc.; J. C. Penney Company, Inc.; Jacobson Brothers/Jacobson Terminals, Inc.; John Fluke Manufacturing Company/Fluke Corporation; K & N Meats; Keller Supply; Kenworth/PACCAR Inc.; King County; Kohkoku USA Inc./Achilles USA, Inc.; Lake Union Drydock Co.; Lake Union Terminal/Wards Cove Packing Company; Lakeside School; Lucks, Oscar; Lucky Stores, Inc.; Manson Construction; Marketime Drugs Inc.; Maust Corporation; Meltec; Meridian Excavating & Wrecking; Metro; Morel Foundry/Morel Industries; National Oceanic and Atmospheric Administration; NC Machinery/SC Distribution Corp.; New Richmond Laundry; Newell, C. A.; Nordstrom Inc.; North Seattle Community College; North Shore; Northwest Home Furniture Mart; Northwest Hospital; Nuclear Pacific Inc./VIOX Corporation; NW Glass/TBG Inc.; NW Tank Service/NW Environmental Services; Oberto Sausage; Olson's Market Foods/Quality Food Centers, Inc.; Olympic Hotel/Four Seasons Hotel/Westin Hotel Company; Olympic Stained Products/Clorox Company/PPG Industries, Inc.; Owens-Corning Fiberglas Corp.; Pacific Fishermen, Inc.; Pacific Iron & Metal;

Pacific Multiform; Pacific Northwest Bell/US West Communications, Inc.; Pacific Partitions; Pampco Construction/ Constructors-Pacific Company; Payless Drugs/Pay N Save/Thrifty Payless, Inc.; Pepsi/Seven-Up Bottling/Glaser Beverage/Alpac Corporation; Peter Pan Seafoods, Inc.; Petschl's Meats; Pike Place Market Authority; Pirates Plunder/Great Western Pacific, Inc.; Plaza 600/The Vance Corporation; Providence Hospital; PSF Industries; Purdy Company; QFC/Quality Food Centers, Inc.; R. C. Hedreen Company; Recreational Equipment, Inc. (REI); Red Dot Corporation; Reynolds Aluminum Corp.; Richardson & Holland/Bunge Foods Corporation; Richmark Printing; Riches & Adams/Adams News Co., Inc.; Rubatino Refuse Removal, Inc.; SAFECO Insurance Company of America; Salmon Terminal/Olympic Steamship Co., Inc.; Sanitary Service Company, Inc./City of Bellingham; Scott Paper Company/ Kimberly Clark Corporation; Scougal Rubber Corporation; Seaboard Lumber; Sealand Service Inc.; Seattle Central Community College; Seattle Community College District; Seattle District Corps of Engineers; Seattle First National Bank/ Seafirst; Seattle Golf & Country Club; Seattle Iron & Metals Corporation; Seattle Post-Intelligencer; Seattle Seafood/Washington Fish & Oyster Company/Ocean Beauty Seafoods, Inc.; Seattle Times; Seattle Trade Center; Seattle University; Sellen Construction Co, Inc.; Skyway Luggage Company; Snohomish County PUD; South Seattle Community College; SQI Roofing/SQI, Inc.; Star Machinery Co.; State of Washington Military Department; Swedish Hospital/Doctors Hospital; Texaco Inc./Texaco Refining & Marketing, Inc.; Thurman Electric & Plumbing Supply; Tiz's Door Sales; Trident Imports; Tullus Gordon Construction/Gordon Tullus Construction; Turner & Pease; U.S. Coast Guard; U.S. Postal Service; United Parcel Service; V.A. Hospitals/U.S. Department of Veterans Affairs; Virginia Mason Hospital; W. G. Clark Construction Co.; W. W. Wells Millworks; Wall & Ceiling Supply; Washington Chain & Supply; Washington Natural Gas Company; Washington Plaza/Seattle Westin Hotel Company/Westin Hotel Company/ Benjamin Franklin Hotel, Inc.; Washington State Ferry; Washington State Liquor Warehouse; Welco Lumber Co.; West Coast Construction; West Waterway Lumber; Western Gear/ Bucyrus-Erie Company; Weyerhaeuser.

The EPA is entering into this agreement under the authority of sections 122(g), 106 and 107 of CERCLA, 42 U.S.C. 9622(g), 9606 and 9607. Section 122(g) authorizes early settlements with *de minimis* parties to allow them to resolve their liabilities at Superfund sites without incurring substantial transaction costs. Under this authority, the agreement proposes to settle with parties in the Tulalip Landfill case who each are responsible for less than 0.6% of the volume of hazardous substances at the site.

In February and March 1988, EPA contractor Ecology & Environment, Inc. (E&E) performed a site inspection of the landfill for NPL evaluation. The inspection revealed groundwater contamination with unacceptably high levels of arsenic, barium, cadmium, chromium, lead, mercury, and silver. Water samples taken in the wetlands adjacent to the site showed exceedences of marine chronic criteria for cadmium, chromium, and lead as well as exceedences in marine acute criteria for copper, nickel and zinc. In addition, a variety of metals were found in on-site pools and leachate. The study concluded that contamination was migrating off site. On July 29, 1991, EPA proposed adding the Tulalip Landfill to the NPL, and on April 25, 1995, with the support of the Governor of the State of Washington and the Tulalip Tribes of Washington, EPA published the final rule adding the Site to the NPL.

EPA is currently performing a Remedial Investigation (''RI'') and Feasibility Study (''FS'') pursuant to an Administrative Order on Consent with several potentially responsible parties. The FS is being conducted in two parts. The first part, which has been completed, evaluates various containment alternatives for the landfill source area, which includes approximately 147 acres in which waste was deposited. The second part will evaluate the off-source areas, which includes the wetlands and tidal channels that surround the landfill source area. On March 1, 1996, EPA issued a Record of Decision that selected an interim remedial action for the source area. The selected interim remedy requires installation of an engineered, low permeability cover over the source area of the landfill, at an estimated cost of $25.1 million. For purposes of this settlement, EPA estimates that the expected future response costs at the Site will be $33,543,626, including EPA's oversight costs.

The proposed settlement requires each settling party to pay a fixed sum of money representing their volumetric share of EPA's past costs and the estimated costs of future response actions, plus a premium. The total amount that may be recovered from the proposed settlement is $8,130,610. Of the amount paid, $270,905 will reimburse a share of response costs incurred by EPA at the Site, and $7,859,705 will be deposited in the Tulalip Landfill Special Account within the EPA Hazardous Substance Superfund to be retained and used to conduct or finance response actions at or in connection with the Site. Upon full payment, each settling party will receive a release from further civil or administrative liabilities for the Site and statutory contribution protection under Section 122(g)(5), 42 U.S.C. 9622(g)(5).

EPA will receive written comments relating to this proposed settlement for a period of thirty (30) days from the date of this publication.

The proposed agreement may be obtained from Cindy Colgate, Office of Environmental Cleanup (ECL–113), 1200 Sixth Avenue, Seattle, Washington 98101, (206) 553–1815. The Administrative Record for this settlement may be examined at the EPA's Region 10 office located at 1200 Sixth Avenue, Seattle, Washington 98101 by contacting Lynn M. Williams, Superfund Records Manager, Office of Environmental Cleanup (ECL–113), 1200 Sixth Avenue, Seattle, Washington 98101, (206) 553–2121.

Authority: The Comprehensive Environmental Response, Compensation and Liability Act, as amended, 41 U.S.C. Sections 9601–9675.

Jane S. Moore,

Acting Regional Administrator.

[FR Doc. 96–17325 Filed 7–8–96; 8:45 am]

BILLING CODE 6560–50–P

[FRL–5532–9]

Clean Water Act Section 303(d): Availability of List Submissions and Proposed Decisions

AGENCY: Environmental Protection Agency.

ACTION: Notice of Availability.

SUMMARY: This notice announces the availability of lists submitted to EPA by California and Hawaii pursuant to Clean Water Act Section 303(d)(2) as well as EPA's proposed decisions regarding these submissions, and requests public comment. Section 303(d)(2) requires that states submit and EPA approve or disapprove lists of waters for which existing technology-based pollution controls are not stringent enough to attain or maintain state water quality standards and for which total maximum daily loads (TMDLs) must be prepared.

On June 14, 1996, EPA partially approved California's submittal.

Specifically, EPA approved California's listing of waters except for waters listed in the Santa Ana Region of California. Today, EPA is proposing to:

(1) approve California's 303(d) submission of waters in the Santa Ana Region,

(2) disapprove California's decisions not to list Ten Mile River for sediment and Navarro River, which is already listed for sediment, for temperature,

(3) add the Ten Mile River for sediment and the Navarro River for temperature to California's 1996 303(d) list, and

(4) approve Hawaii's 303(d) submission.

EPA is providing the public the opportunity to review these proposed decisions as required by Public Participation regulations [40 CFR Part 25]. EPA will consider public comments in reaching its final decisions on California and Hawaii's final lists.

DATES: Comments must be submitted to EPA on or before August 8, 1996.

ADDRESSES: Comments on the proposed decisions should be sent to David Smith, TMDL Coordinator, Water Division, U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105, telephone (415) 744–2012, facsimile (415) 744–1078. Copies of the proposed decisions concerning California and Hawaii which explain the rationale for EPA's proposed decisions can be obtained by writing or calling Mr. Smith at the above address. Underlying documentation comprising the record for this decision is available for public inspection at the above address.

FOR FURTHER INFORMATION CONTACT: David Smith at (415) 744–2012.

SUPPLEMENTARY INFORMATION: Section 303(d) of the Clean Water Act (CWA) requires that each state identify those waters for which existing technology-based pollution controls are not stringent enough to attain or maintain state water quality standards. For those waters, states are required to establish TMDLs according to a priority ranking.

On January 11, 1985, EPA published the Water Quality Planning and Management regulations [50 FR 1775]. These regulations included requirements related to the implementation of Section 303(d) of the CWA [40 CFR 130.7]. The regulations did not specify dates for state compliance with the Section 303(d) requirements, but reiterated the statutory provisions calling for submissions from time to time. On July 24, 1992, EPA published a final rule [57 FR 143] that amended 40 CFR 130.7 to establish that, for the purposes of identifying water quality-limited waters still requiring TMDLs, ''from time to time'' means once every two years. The list of waters still needing TMDLs must also include a priority ranking and must identify the waters targeted for TMDL development during the next two years [40 CFR 130.7].

Consistent with EPA's revised regulations, California submitted to EPA for its approval its listing decisions under Section 303(d)(2). EPA today proposes to:

(1) decline to make a final decision to approve the listings and priority rankings for the Santa Ana RWQCB (Region 8) because that Regional Board provided insufficient opportunity for public participation, and instead propose to approve the listings and priority rankings, with EPA's final decision to approve or disapprove to be issued after consideration of public comment, (2) propose disapproval of the State's decision not to list Ten Mile River for sediment and Navarro River for temperature, and (3) propose a final decision to add Ten Mile River for sediment and Navarro River for temperature to the State's 1996 list and establish appropriate priority rankings.

EPA solicits public comment on California's list of waters in the Santa Ana Region and EPA's proposed decision to approve these listings, EPA's proposed decision to disapprove California's decisions concerning Ten Mile River and Navarro River, and EPA's proposed decision to add the Ten Mile River for sediment and the Navarro River for temperature to California's final 1996 Section 303(d) list.

Hawaii also submitted to EPA for its approval its listing decisions under Section 303(d)(2). EPA today proposes to fully approve Hawaii's list of waters needing TMDLs, priority rankings, and list of waters targeted for TMDL development during the next two years. EPA solicits public comment on Hawaii's lists and EPA's proposed approval decision.

EPA notes that it does not normally solicit public comment on its decisions to approve state Section 303(d) lists. Pursuant to the public participation requirements of 40 CFR 25, EPA is providing this opportunity for public review and comment on its proposed approval decisions because California provided inadequate opportunity for public comment during development of its lists for the Santa Ana Region, and Hawaii provided no opportunity for public comment during the development of its lists. In the future, EPA expects that states will provide adequate opportunities for public comment during development of the state lists.

Dated: June 14, 1996.

John Ong,

Acting Director, Water Management Division.

[FR Doc. 96–17321 Filed 7–8–96; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL LABOR RELATIONS AUTHORITY

Sunshine Act Meeting

TIME AND DATES: 2:00 p.m., Tuesday, July 16, 1996.

PLACE: Second Floor Agenda Room, 607 14th Street, N.W., Washington, D.C. 20424.

STATUS: Open. Attendance at the meeting will be limited because of space constraints. Persons interested in attending the meeting should notify the Office of Case Control. Telephone: FTS or Commercial (202) 482–6540.

MATTERS TO BE CONSIDERED: The Federal Labor Relations Authority is holding oral argument in *Social Security Administration, Baltimore, Maryland,* Case No. 3–CA–10859. The proceeding concerns the extent to which an agency is obligated to furnish facilities and services, under 5 U.S.C. § 7116(a)(1) and (3), to a labor organization that is seeking to represent the agency's employees.

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: Notice of Oral Argument and Opportunity to Submit Amicus Curiae Briefs, 61 FR 25871, May 23, 1996.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 10:00 a.m., Wednesday, July 10, 1996.

CONTACT PERSON FOR MORE INFORMATION: James H. Adams, Acting Director, Case Control Office, Federal Labor Relations Authority, 607 14th Street, N.W., Suite 415, Washington, D.C. 20424. Telephone: FTS or Commercial (202) 482–6540.

Dated: July 5, 1996.

For the FLRA.

James H. Adams,

Acting Director, Case Control Office.

[FR Doc. 96–17583 Filed 7–5–96; 1:18 pm]

BILLING CODE 6727–01–P

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Sunshine Act Meeting

July 3, 1996.

TIME AND DATE: 10:00 a.m., Thursday, July 11, 1996.

PLACE: Room 6005, 6th Floor, 1730 K Street, NW., Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following:

1. *C.W. Mining Co.*, Docket No. WEST 92–204. (Issues include whether the Secretary of Labor followed his regulations, criteria, and guidelines in revoking the operator's roof control plan; whether the Secretary consulted in good faith over the roof control plan; and whether the operator's roof control plan was no longer suitable for the mine, the new plan was suitable, and the operator violated 30 C.F.R. § 75.220(a) by operating without an approved plan.)

2. *D.H. Blattner & Sons, Inc.*, Docket Nos. WEST 93–123–M, WEST 93–286–M, and WEST 94–5–RM. (Whether the independent contractor violated 30 C.F.R. § 41.20 by failing to file an operator legal identity report.)

Any person attending this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 C.F.R. § 2706.150(a)(3) and § 2706.160(d).

CONTACT PERSON FOR MORE INFO: Jean Ellen—(202) 653–5629/(202) 708–9300 for TDD Relay/1–800–877–8339 for toll free.

Jean H. Ellen,

Chief Docket Clerk.

[FR Doc. 96–17608 Filed 7–5–96; 3:52 pm]

BILLING CODE 6735–01–M

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have 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 the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they 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 that notice or to the offices of the Board of Governors. Comments must be received not later than July 29, 1996.

A. Federal Reserve Bank of Dallas (Genie D. Short, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. Mercedes Bancorp, Inc. Employee Stock Ownership Plan, Mercedes, Texas; and Trust Company of Texas, trustee, Dallas, Texas, to acquire an additional 7.49 percent, for a total of 20.37 percent, of the voting shares of Mercedes Bancorp, Inc., Mercedes, Texas, and thereby indirectly acquire Mercedes National Bank, Mercedes, Texas.

2. Sarah Blaffer Hrdy, Davis, California; to acquire an additional 4.59 percent, for a total of 19.44 percent, of the voting shares of Texas Gulf Bancshares, Freeport, Texas, and thereby indirectly acquire Texas Gulf Bank, N.A., Freeport, Texas.

Board of Governors of the Federal Reserve System, July 3, 1996.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96–17451 Filed 7–8–96; 8:45 am]

BILLING CODE 6210-01-F

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are 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 standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act, including whether the acquisition of the nonbanking company 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'' (12 U.S.C. 1843). Any request for a hearing 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, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 1, 1996.

A. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. ONB Financial Services, Inc., Ocala, Florida; to become a bank holding company by acquiring 100 percent of the voting shares of Ocala National Bank, Ocala, Florida.

2. South Alabama Bancorporation, Inc., Mobile, Alabama; to merge with First Monco Bancshares, Inc., Monroeville, Alabama, and thereby indirectly acquire The Monroe County Bank, Monroeville, Alabama.

B. Federal Reserve Bank of Chicago (James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. Community Holdings Corporation, Palos Hills, Illinois; to become a bank holding company by acquiring 80 percent of the voting shares of First State Bank and Trust Company of Palos Hills, Palos Hills, Illinois.

Board of Governors of the Federal Reserve System, July 2, 1996.

Jennifer J. Johnson

Deputy Secretary of the Board

[FR Doc. 96–17422 Filed 7-08-96; 8:45 am]

BILLING CODE 6210-01-F

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies That are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.25 of Regulation Y (12 CFR 225.25) or that the Board has determined by Order to be closely

related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for 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 on the question whether the proposal complies with the standards of section 4 of the BHC Act, including 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'' (12 U.S.C. 1843). 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 22, 1996.

A. Federal Reserve Bank of Boston (Robert M. Brady, Vice President) 600 Atlantic Avenue, Boston, Massachusetts 02106:

1. Cambridge Bancorp, Cambridge, Massachusetts; to engage *de novo* through its subsidiary, Cambridge Investment Services of NH, Inc., Cambridge, Massachusetts, in investment advisory activities pursuant to § 225.25(b)(4) of the Board's Regulation Y.

B. Federal Reserve Bank of New York (Christopher J. McCurdy, Senior Vice President) 33 Liberty Street, New York, New York 10045:

1. Deutsche Bank AG, Frankfurt (Main), Federal Republic of Germany; to engage *de novo* through its indirect subsidiary, Deutsche Morgan Grenfell Financial Products Corporation, New York, New York, in trading for its own account, for purposes other than hedging, in U.S. government securities and Eurodollars and options on futures on U.S. government securities and Eurodollars. Notificant proposes to engage in the proposed activities worldwide. The Board previously has determined, by order, that the proposed activities are ''so closely related to banking or managing or controlling banks as to be proper incident thereto.'' *See Swiss Bank Corporation*, 77 Federal Reserve Bulletin 759 (1991). Notificant has stated that Company will conduct the proposed activities subject to the limitations established by the Board in its previous orders.

C. Federal Reserve Bank of San Francisco (Kenneth R. Binning, Director, Bank Holding Company) 101 Market Street, San Francisco, California 94105:

1. Zions Bancorporation, Salt Lake City, Utah; to engage *de novo* through its subsidiary, Cash Access, Inc., Salt Lake City, Utah, a *de novo*, wholly-owned subsidiary, in data processing and data transmission services through the installation and operation of automatic teller machines, pursuant to § 225.25(b)(7) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, July 2, 1996.

Jennifer J. Johnson

Deputy Secretary of the Board

[FR Doc. 96–17423 Filed 7–08–96; 8:45 am]

BILLING CODE 6210-01-F

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies That are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.25 of Regulation Y (12 CFR 225.25) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for 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 on the question whether the proposal complies with the standards of section 4 of the BHC Act, including 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'' (12 U.S.C. 1843). 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 23, 1996.

A. Federal Reserve Bank of New York (Christopher J. McCurdy, Senior Vice President) 33 Liberty Street, New York, New York 10045:

1. Arrow Financial Corporation, Glens Falls, New York; and Arrow Vermont Corporation, Rutland, Vermont, to engage *de novo* in trust activities, pursuant to § 225.25(b)(3) of the Board's Regulation Y.

B. Federal Reserve Bank of Richmond (Lloyd W. Bostian, Jr., Senior Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. Wachovia Corporation, Winston-Salem, North Carolina; to engage *de novo* through it subsidiary, Wachovia Capital Markets, Inc., Atlanta, Georgia, in providing tax planning and preparation services pursuant to § 225.25(b)(21) of the Board's Regulation Y.

C. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. NBN Corp., Newport, Tennessee; to engage *de novo* through it subsidiary, Smoky Mountain Financial Services, Inc., Jefferson City, Tennessee, in consumer finance activities pursuant to § 225.25(b)(1) of the Board's Regulation Y. These activities will be conducted throughout Tennessee.

D. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. Century Bancshares, Inc., Gainesville, Missouri; to engage *de novo* in securities brokerage activities, pursuant to § 225.25(b)(15)(i) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, July 3, 1996.

Jennifer J. Johnson

Deputy Secretary of the Board

[FR Doc. 96–17452 Filed 7–8–96; 8:45 am]

BILLING CODE 6210-01-F

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 11:00 a.m., Monday, July 15, 1996.

PLACE: Marriner S. Eccles, Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, N.W., Washington, D.C. 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: July 5, 1996.

Barbara R. Lowrey,

Associate Secretary of the Board.

[FR Doc. 96–17568 Filed 7–5–96; 11:54 am]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

[File No. 962–3053]

Jordan, McGrath, Case & Taylor; Proposed Consent Agreement with Analysis to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair or deceptive acts or practices and unfair methods of competition, this consent agreement, accepted subject to final Commission approval, would prohibit, among other things, the New York City-based advertising agency from making advertising claims regarding the efficacy, safety, benefits, or performance of any over-the-counter internal analgesics unless they have competent and reliable scientific evidence supporting the claims. The consent agreement settles allegations stemming from Jordan, McGrath's advertising campaign for Doan's pills, an over-the-counter back-pain relief medication marketed by Ciba-Geigy Corporation.

DATES: Comments must be received on or before September 9, 1996.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room 159, 6th St. and Pa. Ave. NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Joel Winston, Federal Trade Commission, S–4002, 6th and Pennsylvania Ave. NW., Washington, DC 20580. (202) 326–3153; Loren Thompson, Federal Trade Commission, S–4002, 6th and Pennsylvania Ave. NW., Washington, DC 20580. (202) 326–2049.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and Section 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the following consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with Section 4.9(b) (6) (ii) of the Commission's Rules of Practice (16 CFR 4.9(b) (6) (ii)).

Agreement Containing Consent Order to Cease and Desist

The Federal Trade Commission, having initiated an investigation of certain acts and practices of Jordan, McGrath, Case & Taylor, Inc., a corporation (hereinafter sometimes referred to as ''proposed respondent''), and it now appearing that proposed respondent is willing to enter into an agreement containing an order to cease and desist from the use of the acts and practices being investigated,

It is hereby agreed by and between Jordan, McGrath, Case & Taylor, Inc., by its duly authorized officer, and counsel for the Federal Trade Commission that:

1. Proposed respondent Jordan, McGrath, Case & Taylor, Inc., is a corporation organized, existing, and doing business under and by virtue of the laws of the State of New York with its office and principal place of business at 445 Park Avenue, New York, New York 10022.

2. Proposed respondent admits all the jurisdictional facts set forth in the draft complaint.

3. Proposed respondent waives:

(a) Any further procedural steps;

(b) The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law; and

(c) All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement.

4. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it, together with the draft of complaint contemplated thereby, will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify proposed respondent, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision, in disposition of this proceeding.

5. This agreement is for settlement purposes only and does not constitute an admission by proposed respondent that the law has been violated as alleged in the draft of complaint, or that the facts as alleged in the draft complaint, other than the jurisdictional facts, are true.

6. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of § 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondent: (1) issue its complaint corresponding in form and substance with the draft complaint and its decision containing the following order to cease and desist in disposition of the proceeding; and (2) make information public in respect thereto. When so entered, the order to cease and desist shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery by the U.S. Postal Service of the complaint and decision containing the agreed-to order to proposed respondent's address as stated in this agreement shall constitute service. Proposed respondent waives any rights it may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or in the agreement may be used to vary or contradict the terms of the order.

7. Proposed respondent has read the proposed complaint and order contemplated hereby. Proposed respondent understands that once the order has been issued, it will be required to file one or more compliance reports showing that it has fully

complied with the order. Proposed respondent further understands that it may be liable for civil penalties in the amount provided by law for each violation of the order after it becomes final.

Order

For purposes of this Order:

1. ''Doan's'' shall mean any over-the-counter internal analgesic drug, as ''drug'' is defined in the Federal Trade Commission Act, bearing the Doan's brand name, including, but not limited to, Regular Strength Doan's analgesic, Extra Strength Doan's analgesic, and Extra Strength Doan's P.M. analgesic.

2. ''Competent and reliable scientific evidence'' shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

I

It is ordered that respondent Jordan, McGrath, Case & Taylor, Inc., a corporation, its successors and assigns, and its officers, agents, representatives and employees, directly or through any partnership, corporation, subsidiary, division or other device, in connection with the advertising, promotion, offering for sale, sale, or distribution of Doan's or any other over-the-counter analgesic drug, in or affecting commerce, as ''drug'' and ''commerce'' are defined in the Federal Trade Commission Act, do forthwith cease and desist from making any representation, in any manner, directly or by implication, that such product is more effective than other over-the-counter analgesic drugs for relieving back pain or any other particular kind of pain, unless, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation. For purposes of Part I of this order, ''competent and reliable scientific evidence'' shall include at least two adequate and well-controlled, double-blinded clinical studies which conform to acceptable designs and protocols and are conducted by different persons, each of whom is qualified by training and experience to conduct such studies, independently of each other.

II

It is further ordered that respondent Jordan, McGrath, Case & Taylor, Inc., a corporation, its successors and assigns, and its officers, agents, representatives and employees, directly or through any partnership, corporation, subsidiary, division or other device, in connection with the advertising, promotion, offering for sale, sale, or distribution of Doan's or any other over-the-counter internal analgesic drug, in or affecting commerce, as ''drug'' and ''commerce'' are defined in the Federal Trade Commission Act, do forthwith cease and desist from making any representation, in any manner, directly or by implication, regarding such product's efficacy, safety, benefits, or performance, unless, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

Provided, however, that it shall be a defense hereunder that the respondent neither knew nor had reason to know of an inadequacy of substantiation for the representation.

III

Nothing in this order shall prohibit respondent from making any representation for any drug that is permitted in labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

IV

It is further ordered that for a period of five (5) years after the last date of dissemination of any representation covered by this order, respondent, or its successors and assigns, shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:

A. All materials that were relied upon in disseminating such representation; and

B. All tests, reports, studies, surveys, demonstrations or other evidence in its possession or control that contradict, qualify, or call into question such representation, or the basis relied upon for such representation, including complaints from consumers.

V

It is further ordered that respondent shall:

A. Within thirty (30) days from the date of entry of this order, provide a copy of this order to each of its current principals, officers, directors and managers, and to all personnel, agents, and representatives having sales, advertising, or policy responsibility with respect to the subject matter of this order; and

B. For a period of ten (10) years from the date of entry of this order, provide a copy of this order to each of its future principals, officers, directors, and managers, and to all personnel, agents, and representatives having sales, advertising, or policy responsibility with respect to the subject matter of this order who are associated with them or any subsidiary, successor, or assign, within three (3) days after the person assumes his or her position.

VI

It is further ordered that respondent shall notify the Commission at least thirty (30) days prior to any proposed change in its corporate structure, including, but not limited to, dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or affiliates, or any other corporate change that may affect compliance obligations arising out of this order.

VII

It is further ordered that this order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

A. Any part in this order that terminates in less than twenty (20) years;

B. This order's application to any respondent that is not named as a defendant in such complaint; and

C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint was never filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

VIII

It is further ordered that respondent shall, within sixty (60) days from the date of entry of this order, and at such other times as the Federal Trade

Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which it has complied with this order.

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted an agreement to a consent order from Jordan, McGrath, Case & Taylor, Inc. (''Jordan, McGrath''), an advertising agency.

The proposed consent order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter concerns Doan's, an analgesic for which Jordan, McGrath created and disseminated advertisements. The Commission's proposed complaint alleges that the respondent represented without a reasonable basis in its advertisements that Doan's analgesic products are more effective than other analgesics, including Bayer, Advil, Tylenol, and Aleve, for relieving back pain. The complaint alleges that respondent knew or should have known that the representation lacked a reasonable basis.

The proposed consent order contains provisions designed to prevent the respondent from engaging in similar acts and practices in the future. Part I of the proposed order prohibits respondent from making any representation that Doan's or any other over-the-counter analgesic drug is more effective than any other such drug for relieving back pain or any other particular kind of pain, unless it possesses competent and reliable scientific evidence, consisting of at least two adequate and well-controlled, double-blinded clinical studies, that substantiates the representation.

Part II of the proposed order prohibits respondent from making any representation about the efficacy, safety, benefits, or performance of any over-the-counter internal analgesic drug, unless it possesses competent and reliable scientific evidence that substantiates the representation. This Part further provides that it shall be a defense under this Part that respondent neither knew nor had reason to know of an inadequacy of substantiation for a representation.

Part III of the order is a safe harbor provision allowing representations for any drug that are permitted in the labeling for that drug under any tentative final or final standard promulgated by the Food and Drug Administration (''FDA'') or by an approved new drug application.

Parts IV, V, VI, and VII of the order relate to respondent's obligation to maintain records, distribute the order to current and future officers and employees, notify the Commission of changes in corporate structure, and file compliance reports with the Commission. Part VIII provides that the order will terminate after twenty years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Donald S. Clark,

Secretary.

[FR Doc. 96–17466 Filed 7–8–96; 8:45 am]

BILLING CODE 6750–01–P

[File No. D–9274]

RustEvader Corporation; David F. McCready; Proposed Consent Agreement With Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair or deceptive acts or practices and unfair methods of competition, this consent agreement, accepted subject to final Commission approval, would require, among other things, the Altoona, Pennsylvania-based former owner and president of RustEvader Corporation to pay $200,000 in consumer redress and would prohibit him from using the names ''Rust Evader'' or ''Rust Buster'' for any device that he markets as reducing corrosion in motor vehicle bodies. McCready is also prohibited from making any claims about the performance, efficacy, or attributes of any product for use in motor vehicles without having appropriate substantiation to back up the claim and from misrepresenting the existence or results of any test or study. The consent agreement settles allegations stemming from advertising for RustEvader's ''Rust Evader'' device that purportedly reduced corrosion in motor vehicle bodies.

DATES: Comments must be received on or before September 9, 1996.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room 159, 6th St. and Pa. Ave., N.W., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Michael Milgrom, Federal Trade Commission, Cleveland Regional Office, 668 Euclid Avenue, Suite 520–A, Cleveland, OH 44114. (216) 522–4210.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and Section 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the following consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with Section 4.9(b) (6) (ii) of the Commission's Rules of Practice (16 CFR 4.9(b) (6) (ii)).

AGREEMENT WITH DAVID F. McCready Containing Consent Order to Cease and Desist

The agreement herein, by and between David F. McCready, individually and as an officer of RustEvader Corporation, a/k/a Rust Evader Corporation, sometimes d/b/a/ REC Technologies, a corporation, hereinafter sometimes referred to as respondent, and his attorney, and counsel for the Federal Trade Commission, is entered into in accordance with the Commission's Rule governing consent order procedures. In accordance therewith the parties hereby agree that:

1. RustEvader Corporation, a/k/a Rust Evader Corporation, sometimes d/b/a REC Technologies (REC)is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Pennsylvania, with its office and principal place of business located at 1513 Eleventh Avenue, Altoona, Pennsylvania 16603.

Respondent David F. McCready has been an owner, officer and director of said corporation. At times material to the complaint herein, he formulated, directed, and controlled the policies, acts, and practices of said corporation. His address is RD 4 Box 92 B, Altoona, Pennsylvania 16601.

2. Respondent has been served with a copy of the complaint issued by the Federal Trade Commission charging him with violations of Section 5(a) of the Federal Trade Commission Act (15 U.S.C. § 45(a)) and of Section 102(c) of the Magnuson-Moss Warranty-Federal Trade Commission Improvement Act (15 U.S.C. § 2302(c)), and has filed an

answer to said complaint denying said charges.

3. Respondent admits all the jurisdictional facts set forth in the Commission's complaint in this proceeding.

4. Respondent waives:

(a) Any further procedural steps;

(b) The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law;

(c) All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement; and

(d) Any claim under the Equal Access to Justice Act.

5. This agreement shall not become a part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission it will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify the respondent, in which event it will take such action as it may consider appropriate, or issue and serve its decision, in disposition of the proceeding.

6. This agreement is for settlement purposes only and does not constitute an admission by respondent that the law has been violated as alleged in the complaint, or that the facts as alleged in the complaint, other than jurisdictional facts, are true.

7. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 3.25(f) of the Commission's Rules, the Commission may without further notice to respondent, (1) issue its decision containing the following order to cease and desist in disposition of the proceeding, and (2) make information public in respect thereto. When so entered, the order to cease and desist shall have the same force and effect and may be altered, modified or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery by the U.S. Postal Service of the decision containing the agreed-to order to respondent's address as stated in this agreement shall constitute service. Respondent waives any right he might have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or in the agreement may be used to vary or to contradict the terms of the order.

8. Respondent has read the complaint and the order contemplated hereby. He understands that once the order has been issued, he will be required to file one or more compliance reports showing that he has fully complied with the order. Respondent further understands that he may be liable for civil penalties in the amount provided by law for each violation of the order after it becomes final.

Order

* * * * *

Definitions

For the purposes of this Order, the following definitions shall apply:

A. ''Electronic corrosion control device'' shall mean any device or mechanism that is intended, through the use of electricity, static or current, to control, retard, inhibit or reduce corrosion in motor vehicles.

B. ''Rust Evader'' shall mean the electronic corrosion control device sold under the trade names Rust Evader, Rust Buster, Electro-Image, Eco-Guard, and any other substantially similar product sold under any trade name.

C. ''Competent and reliable scientific evidence'' shall mean tests, analyses, research, studies, or other evidence, based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

I

It is ordered that respondent David F. McCready, individually and as an officer of RustEvader Corporation, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, packaging, labeling, advertising, promotion, offering for sale, sale, or distribution of the Rust Evader, in or affecting commerce, as ''commerce'' is defined in the Federal Trade Commission Act, shall forthwith cease and desist from representing, in any manner, directly or by implication, that such product is effective in preventing or substantially reducing corrosion in motor vehicle bodies.

II

It is further ordered that respondent David F. McCready, individually and as an officer of RustEvader Corporation, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, packaging, labeling, advertising, promotion, offering for sale, sale, or distribution of any product for use in motor vehicles in or affecting commerce, as ''commerce'' is defined in the Federal Trade Commission Act, shall forthwith cease and desist from making any representation, directly or by implication, concerning the performance, efficacy or attributes of such product unless such representation is true and, at the time such representation is made, respondent possesses and relies upon competent and reliable evidence, which, when appropriate, must be competent and reliable scientific evidence, that substantiates the representation.

III

It is further ordered that respondent David F. McCready, individually and as an officer of RustEvader Corporation, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, packaging, labeling, advertising, promotion, offering for sale, sale, or distribution of any product for use in motor vehicles in or affecting commerce, as ''commerce'' is defined in the Federal Trade Commission Act, shall forthwith cease and desist from misrepresenting, in any manner, directly or by implication, the existence, contents, validity, results, conclusions, interpretations or purpose of any test, study, or survey.

IV

It is further ordered that respondent David F. McCready, individually and as an officer of RustEvader Corporation, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, packaging, labeling, advertising, promotion, offering for sale, sale, or distribution of any product for use in motor vehicles in or affecting commerce, as ''commerce'' is defined in the Federal Trade Commission Act, shall forthwith cease and desist from misrepresenting, in any manner, directly or by implication, that any demonstration, picture, experiment or test proves, demonstrates or confirms any material quality, feature or merit of such product.

V

It is further ordered that respondent David F. McCready, individually and as an officer of RustEvader Corporation, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, packaging, labeling, advertising,

promotion, offering for sale, sale, or distribution of the Rust Evader in or affecting commerce, as ''commerce'' is defined in the Federal Trade Commission Act, shall forthwith cease and desist from employing the terms Rust Evader or Rust Buster in conjunction with or as part of the name for such product or the product logo.

VI

It is further ordered that respondent David F. McCready, individually and as an officer of RustEvader Corporation, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, packaging, labeling, advertising, promotion, offering for sale, sale, or distribution of any consumer product in or affecting commerce, as ''commerce'' is defined in the Federal Trade Commission Act and actually costing the consumer more than five dollars ($5.00), shall forthwith cease and desist from conditioning any written or implied warranty of such product on the consumer's purchase or use, in connection with such product, of any article or service (other than article or service provided without charge under the terms of the warranty) which is identified by brand, trade, or corporate name.

VII

It is further ordered that respondent David F. McCready, individually and as an officer of RustEvader Corporation, his successors and assigns, shall be liable for consumer redress in the amount of two hundred thousand dollars ($200,000.00) as provided herein:

A. Not later than five (5) days from the date this Order becomes final, respondent shall deposit into an escrow account to be established by the Commission for the purpose of receiving payment due under this Order (''Commission escrow account''), the sum of two hundred thousand dollars ($200,000.00).

B. Provided however, that if, at the time this Order becomes final, respondent has not completed the sale of respondent's property known as RD 4 Box 92B, Altoona, Pennsylvania 16601, then respondent shall deposit, into the Commission escrow account, not later than five (5)days from the date this Order becomes final, the sum of forty thousand dollars ($40,000.00). Respondent shall deposit the remaining one hundred sixty thousand dollars ($160,000.00) into the Commission escrow account upon the sale of respondent's property known as RD 4 Box 92B, Altoona, Pennsylvania 16601 at the time of the sale of said property or six months from the date that this Order becomes final, whichever first occurs. Respondent shall provide security for the one hundred sixty thousand dollars ($160,000.00) by means of a mortgage on the property known as RD 4 Box 92B, Altoona, Pennsylvania 16601. Such mortgage shall be in a form, and shall be entered into by such date as agreed to by the parties, but no later than five (5) days from the date this Order becomes final.

C. In the event of any default in payment to the Commission escrow account, which default continues for more than ten (10) days beyond the date of payment, respondent shall also pay interest as computed under 28 U.S.C. Section 1961, which shall accrue on the unpaid balance from the date of default until the date the balance is fully paid.

D. The funds deposited by respondent in the Commission escrow account, together with accrued interest, shall, in the discretion of the Commission, be used by the Commission to provide direct redress to purchasers of the Rust Evader in connection with the acts or practices alleged in the complaint, and to pay any attendant costs of administration. If the Commission determines, in its sole discretion, that redress to purchasers of this product is wholly or partially impracticable or is otherwise unwarranted, any funds not so used shall be paid to the United States Treasury. Respondent shall be notified as to how the funds are distributed, but shall have no right to contest the manner of distribution chosen by the Commission. No portion of the payment as herein provided shall be deemed a payment of any fine, penalty, or punitive assessment.

E. At any time after this Order becomes final, the Commission may direct the agent for the Commission escrow account to transfer funds from the escrow account, including accrued interest, to the Commission to be distributed as herein provided. The Commission, or its representative, shall, in its sole discretion, select the escrow agent.

F. Respondent relinquishes all dominion, control and title to the funds paid into the Commission escrow account, and all legal and equitable title to the funds vests in the Treasurer of the United States and in the designated consumers. Respondent shall make no claim to or demand for return of the funds, directly or indirectly, through counsel or otherwise; and in the event of bankruptcy of respondent, respondent acknowledges that the funds are not part of the debtor's estate, nor does the estate have any claim or interest therein.

VIII

It is further ordered that for five (5) years after the last date of dissemination of any representation covered by this Order, respondent David F. McCready, or his successors and assigns, shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:

I. All materials that were relied upon in disseminating such representation; and

B. All tests, reports, studies, surveys, demonstrations or other evidence in their possession or control that contradict, qualify, or call into question such representation, or the basis relied upon for such representation, including complaints from consumers.

IX

It is further ordered that respondent David F. McCready shall, for a period of ten (10) years from the date of issuance of this Order, notify the Federal Trade Commission within thirty (30) days of the discontinuance of his present business or employment and of his affiliation with any new business or employment. Each notice of affiliation with any new business or employment shall include the respondent's new business address and telephone number, current home address, and a statement describing the nature of the business or employment and his duties and responsibilities.

X

It is further ordered that this Order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the Order, whichever comes later; provided, however, that the filing of such complaint will not affect the duration of:

A. Any paragraph in this Order that terminates in less than twenty (20) years;

B. This Order's application to any respondent that is not named as a defendant in such complaint; and

C. This Order if such complaint is filed after the Order has terminated pursuant to this paragraph.

Provided further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the

Order will terminate according to this paragraph as though the complaint was never filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

XI

It is further ordered that respondent David F. McCready shall, within sixty (60) days after the date of service of this Order, file with the Commission a report, in writing, setting forth in detail the manner and form in which he has complied with this Order.

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a proposed consent order from David F. McCready (McCready).

On August 30, 1995, the Commission issued an administrative complaint in this matter (described below). The administrative complaint was withdrawn from adjudication, with respect to McCready, on April 11, 1996, for the purpose of considering the proposed consent agreement.

The proposed consent order has been placed on the public record for sixty (60) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and take other appropriate action, or make final the proposed order contained in the agreement.

This matter concerns advertisements and other promotional practices by Rust Evader Corporation (REC) in connection with the promotion and sale of the Rust Evader, a device purported to reduce corrosion in motor vehicle bodies. The complaint alleges that McCready directed, formulated and controlled the acts and practices of REC during the period when the violations occurred.

The complaint alleges that REC and McCready engaged in deceptive advertising in violation of Section 5 of the Federal Trade Commission Act by falsely claiming that the Rust Evader is effective to substantially reduce corrosion in motor vehicle bodies. The complaint also alleges that the advertising implied, falsely, that REC and McCready had scientific substantiation for this claim.

The complaint also alleges that REC and McCready used a product demonstration of the Rust Evader that was deceptive because it used conditions that an automobile would not encounter in practice and that improved the operation of the device. The complaint also alleges that the respondents used test results to promote the Rust Evader with the representation that such test results constituted scientific proof of the efficacy of the device. In fact, according to the complaint, the test results did not constitute such proof.

The complaint also alleged that REC and McCready violated Section 102(c) of the Magnuson-Moss Warranty Act by using a warranty that was conditioned on the consumer having the Rust Evader inspected every two years and that required the consumer to pay for the inspection.

Finally, the complaint alleged that REC and McCready provided the means and instrumentalities for others to violate Section 5 of the Federal Trade Commission Act.

The proposed consent order contains provisions designed to prevent misrepresentations related to these specific matters and others. Part I of the order prohibits McCready from representing that the Rust Evader is effective in preventing or substantially reducing corrosion in motor vehicle bodies.

Part II prohibits McCready from making any representation concerning the performance, efficacy or attributes of a product intended for use with motor vehicles unless there is competent and reliable evidence to substantiate the representation.

Part III prohibits McCready from misrepresenting the existence, contents, validity, results, conclusions, interpretations or purpose of any test, study, or survey in connection with the sale or advertising of any product for use in motor vehicles.

Part IV prohibits McCready from misrepresenting, in connection with the sale of any product for use in motor vehicles, that any demonstration, picture, experiment or test proves, demonstrates or confirms any material quality, feature or merit of such product.

Part V prohibits McCready from using the names Rust Evader and Rust Buster in connection with future sale of the Rust Evader or any substantially similar product.

Part VI prohibits future violations of Section 102(c) of the Magnuson-Moss Warranty Act.

Part VII requires McCready to pay the sum of $200,000 to provide a fund for redress of consumers who purchased the Rust Evader. McCready will pay $40,000 within five days of final issuance of the order by the Commission, and will pay the remaining $160,000 no later than six months after final issuance of the order. His obligation to pay the latter sum will be secured by a mortgage on real estate he now owns.

Parts VIII, IX, and XI are compliance and reporting provisions that require McCready to: retain all records that would bear on his compliance with the order, notify the Commission of any changes in his business affiliation, and report to the Commission his compliance with the terms of the order.

Part X provides that the order will terminate automatically twenty years from the date it becomes final unless the Commission has brought an action in federal court alleging a violation of the order. In that case, the order will terminate twenty years from the date that the federal court action is filed.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Donald S. Clark,

Secretary.

[FR Doc. 96–17465 Filed 7–8–96; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Health Care Policy and Research

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Agency for Health Care Policy and Research, HHS.

ACTION: Notice.

SUMMARY: This notice announces the Agency for Health Care Policy and Research's (AHCPR) intention to request the Office of Management and Budget (OMB) review of a proposed data collection project. In accordance with the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3507(a)(1)(D)), the AHCPR invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by August 8, 1996.

ADDRESSES: Written comments should be submitted to: Allison Eydt, Human Resources and Housing Branch, Office of Information and Regulatory Affairs, OMB, New Executive Office Building, Room 10235; Washington, D.C.

All comments will become a matter of public record.

FOR FURTHER INFORMATION CONTACT: Carole Dillard, AHCPR Reports Clearance Officer, (301) 594–1357.

SUPPLEMENTARY INFORMATION:

Proposed Project

Evaluation of the kiosk-based ChoiceCard. The purpose of the ChoiceCard project is to develop a kiosk-based automated application to assist Medicaid recipients in selecting and enrolling in a health plan. The proposed data collection will provide an assessment of the usability of the kiosk-based automated application in Medicaid eligibility offices and provide an assessment of the application by Medicaid recipients. The application will be assessed in terms of its effectiveness in helping the recipient identify/select a personal doctor (PCP/OB/Gyn), learn with which plan(s) a particular doctor is affiliated, understand benefits coverage, understand managed care concept and requirements, identify/select a plan that meets their needs, and enroll in a plan. Burden estimates follow:

	Consumer
No. of respondents	200.
No. of surveys per respondent	1.
Average burden/response	.25 hours.
Estimated total burden/response.	50 hours.

Copies of these data collection plans and instruments can be obtained from the AHCPR Reports Clearance Officer (see above for details).

Dated: June 28, 1996.

Clifton R. Gaus,

Administrator.

[FR Doc. 96–17316 Filed 7–8–96; 8:45 am]

BILLING CODE 4160–90–M

Centers for Disease Control and Prevention

The National Institute for Occupational Safety and Health (NIOSH) Scientific and Technical Meetings on Occupational Exposure to Asphalt During Roofing and Paving Operations: Correction

Federal Register Citations of Previous Announcements: 61 FR 28590–28591—dated June 5, 1996, and 61 FR 30242—dated June 14, 1996.

SUMMARY: Notice is given that the purpose of these meetings on July 8–10, 1996, and July 22–24, 1996, has been restructured to address only those issues relevant to the control of asphalt exposures (e.g., engineering controls, work practices). The draft NIOSH ''Working Paper on Occupational Exposure to Asphalt'' will not be discussed at these meetings. The meeting times, dates, place, and status remain unchanged.

CONTACT PERSON FOR MORE INFORMATION: Diane Manning, NIOSH Docket Office, 4676 Columbia Parkway, M/S C–34, Cincinnati, Ohio 45226.

Dated: July 2, 1996.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–17389 Filed 7–8–96; 8:45 am]

BILLING CODE 4160–19–M

Health Resources and Services Administration

Maternal and Child Health Bureau; Special Project Grants; Maternal and Child Health (MCH) Services; Community Integrated Service Systems (CISS) Set-Aside Program; Community-Based Intervention Research Grants

AGENCY: Health Resources and Services Administration (HRSA).

ACTION: Notice of availability of funds.

SUMMARY: The HRSA announces that applications will be accepted for fiscal year (FY) 1996 funds for Maternal and Child Health (MCH) Community Integrated Service Systems (CISS) grants to support community-based intervention research. The purpose of these projects is to support research on CISS-sponsored early intervention services programs in the context of developing and expanding local service delivery systems. Awards are made under the program authority of Section 502(b)(1)(A) of the Social Security Act, the CISS Federal Set-Aside Program. Within the HRSA, CISS projects are administered by the Maternal and Child Health Bureau (MCHB).

About $900,000 will be available to support up to 3 new projects at an average of about $300,000 per award per year. The actual amounts available for awards and their allocation may vary, depending on the volume and quality of applications. Awards are made for grant periods of not more than 4 years in duration. Funds are appropriated by Public Law 104–134.

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 for setting priority areas. The CISS Federal Set-Aside Program addresses issues related to the *Healthy People 2000* objectives of improving maternal, infant, child and adolescent health and developing service systems for children with special health care needs. Potential applicants may obtain 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) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325 (telephone: 202 783–3238).

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

ADDRESSES: Grant applications for MCH research and training grants must be obtained from and submitted to: Chief, Grants Management Branch, Office of Operations and Management, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18–12, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443–1440. Applicants for these projects will use application Form PHS 398 (Rev. 5/95), approved by the Office of Management and Budget (OMB) 0925–0001. An MCHB supplement, with instructions specifically applicable to Community-Based Intervention Research Grants, is included in the application package, which can be obtained from the address given above. You must obtain application materials in the mail.

Federal Register notices and application guidance for MCHB programs are available on the World Wide Web via the Internet at address: http://www.os.dhhs.gov/hrsa/mchb. Click on the file name you want to download to your computer. It will be saved as a self-extracting (Macintosh or) Wordperfect 5.1 file. To decompress the file once it is downloaded, type in the file name followed by a <return>. The file will expand to a Wordperfect 5.1 file. If you have difficulty accessing the MCHB Home Page via the Internet and need technical assistance, please contact Linda L. Schneider at 301–443–0767 or ''lschneider@hrsa.ssw.dhhs.gov''.

DATES: Potential applicants are invited to request application packages and to submit their applications for funding consideration. The application deadline is August 26, 1996.

Applications will be considered to have met the deadline if they are either: (1) received on or before the deadline date, or (2) postmarked on or before the deadline date and received in time for orderly processing. Applicants should request a legibly dated receipt from a commercial carrier or the U.S. Postal Service, or obtain a legibly dated U.S. Postal Service postmark. Private metered postmarks will not be accepted as proof of timely mailing. Late applications or those sent to an address other than specified in the ADDRESS section will be returned to the applicant.

FOR FURTHER INFORMATION CONTACT: For programmatic or technical information, contact Dr. Gontran Lamberty, Director, MCH Research Program, Research and Training Branch, MCHB, 5600 Fishers Lane, Room 18A–55, Rockville, MD 20857, telephone: 301 443–2190. For information concerning business management issues, contact Ms. Constance Davenport, Grants Management Branch, MCHB, Room 18–12, 5600 Fishers Lane, Rockville, MD, telephone 301 443–1440.

SUPPLEMENTARY INFORMATION:

1. Program Background and Objectives

The purpose of the Community-Based Intervention Research Grant projects covered by this announcement is to generate new knowledge on early intervention services models and on how to integrate these models into existing systems of care at the community level while sustaining the essential nature and demonstrated effectiveness of the original prototypes.

Intervention is the name given to a variety of programs and clinical management approaches designed to improve adverse conditions in individuals and groups or prevent or limit these conditions. From the standpoint of research, interventions are scientific experiments in which an investigator, through a particular effort, treatment, or program, seeks to purposively influence an outcome or outcomes in an individual or group under controlled conditions. Intervention studies may also be viewed as prospective, formal investigations of prototypes of programs or subcomponents of programs (e.g., outreach, one-stop shopping or home visiting). These prototypes, if proven effective under controlled conditions, are then ready for further testing and refinement in real-life settings.

2. Special Concerns

In its administration of the MCH Services Block Grant, the MCHB places special emphasis on improving service delivery to women and children from racial and ethnic minority populations who have had limited access to accessible care. This means that CISS projects are expected to serve and appropriately involve in project activities individuals from the populations to be served, unless there are compelling programmatic or other justifications for not doing so. The MCHB's intent is to ensure that project interventions are responsive to the cultural and linguistic needs of special populations, that services are accessible to consumers, and that the broadest possible representation of culturally distinct and historically underrepresented groups is supported through programs and projects sponsored by the MCHB. This same special emphasis applies to improving service delivery to children with special health care needs.

In keeping with the goals of advancing the development of human potential, strengthening the Nation's capacity to provide high quality education by broadening participation in MCHB programs of institutions that may have perspectives uniquely reflecting the Nation's cultural and linguistic diversity, and increasing opportunities for all Americans to participate in and benefit from Federal public health programs, a funding priority will be placed on projects from Historically Black Colleges and Universities (HBCU) or Hispanic Serving Institutions (HSI) in all categories and subcategories in this notice for which applications from academic institutions are encouraged. An approved proposal from a HBCU or HSI will receive a 0.5 point favorable adjustment of the priority score in a 5=point range before funding decisions are made.

3. Project Review and Funding

Within the limit of funds determined by the Secretary to be available for the activities described in this announcement, the Secretary will review applications for funds as competing applications and may award Federal funding for projects which will, in her judgment, best promote the purpose of title V of the Social Security Act, with special emphasis on improving service delivery to women and children from culturally distinct populations; best address achievement of *Healthy People 2000* objectives related to maternal, infant, child and adolescent health and service systems for children at risk of chronic and disabling conditions; and otherwise best promote improvements in maternal and child health.

4. Criteria for Review

The criteria which follow are used, as pertinent, to review and evaluate applications for CISS awards announced in this notice. Further guidance in this regard is supplied in application guidance materials, which may specify other criteria.

—The quality of the project plan or methodology.
—The need for the research or training.
—The extent to which the project will contribute to the advancement of maternal and child health and/or improvement of the health of children with special health care needs;
—The extent to which the project is responsive to policy concerns applicable to MCH grants and to program objectives, requirements, priorities and/or review criteria for specific project categories, as published in program announcements or guidance materials.
—The extent to which the estimated cost to the Government of the project is reasonable, considering the anticipated results.
—The extent to which the project personnel are well qualified by training and experience for their roles in the project and the applicant organization has adequate facilities and personnel.
—The extent to which, insofar as practicable, the proposed activities, if well executed, are capable of attaining project objectives.
—The strength of the project's plans for evaluation.
—The extent to which the project will be integrated with the administration of the MCH Block Grant, State primary care plans, public health, and prevention programs, and other related programs in the respective State(s).
—The extent to which the application is responsive to the special concerns and program priorities specified in this notice.

Comments on this notice which members of the public wish to make are welcome at any time and may be submitted to: Director, MCHB, at the address listed in the **ADDRESSES** section. Suggestions will be considered when priorities are developed for the next solicitation.

5. Grants/Amounts

A total of about $900,000 per year will be available to support a maximum of 3 projects. The project period will not exceed 4 years.

6. Eligible Applicants

Applicants eligible to compete are public or nonprofit institutions of higher learning and public or nonprofit private agencies and organizations engaged in research or in maternal and child health or children with special health care needs programs.

7. Public Health System Reporting Requirements

This program is subject to the Public Health System Reporting Requirements (approved under OMB No. 0937–0195). Under these requirements, the community-based nongovernmental applicant must prepare and submit a Public Health System Impact Statement (PHSIS). The PHSIS is intended to provide information to state and local health officials to keep them apprised of proposed health services grant applications submitted by community-based nongovernmental organizations within their jurisdictions. Community-based nongovernmental applicants are required to submit the following information to the head of the appropriate State and local health agencies in the area(s) to be impacted no later than the Federal application receipt date: (1) A copy of the face page of the application (PHS–398 (Rev. 5/95); (2) a summmary of the project PHSIS, not to exceed one page, which provides a description of the population to be served, a summary of the services to be provided, and a description of the coordination planned with the appropriate State and local health agencies.

8. Executive Order 12372

The CISS Federal Set-Aside Program has been determined to be a program which is not subject to the provisions of Executive Order 12372 concerning intergovernmental review of Federal programs.

The OMB Catalog of Federal Domestic Assistance number is 93.110.

Dated: July 1, 1996.

Ciro V. Sumaya,

Administrator.

[FR Doc. 96–17317 Filed 7–8–96; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4086–N–01]

Office of Administration; Submission for OMB Review Comment Request

AGENCY: Office of Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due date: August 8, 1996.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within thirty (30) days from the date of this Notice. Comments should refer to the proposal by name and/or OMB approval number should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Kay F. Weaver, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 708–0050. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Ms. Weaver.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: June 25, 1996.

David S. Cristy,

Acting Director, Information Resources, Management Policy and Management Division.

Title of Proposal: Conveyance (Acquisition) and Disposition Information Collections contained in Handbook 4310.5 entitled ''Property Disposition Handbook, One-to-Four Family Properties''.

Office: Housing.

OMB Approval Number: 2502–0306.

Description of the Need for the Information and Its Proposed Use: These information collections are needed to determine the condition of the property upon conveyance, to determine the results of the repair contracts, and to monitor the contractor's performance in maintaining the properties. The sales contracts will be used as binding contracts between the purchaser and HUD. Respondents are potential contractors, contractors who work for HUD, and potential and actual purchasers of HUD-owned properties.

Form Number: HUD–9516A, 9519, 9519A, 9544, 9548, and 9733.

Respondents: Business or other for-profit, individuals or households, not-for-profit institutions, and the Federal Government.

Frequency of Submission: On occasion.

Reporting Burden:

	Number of respondents	x	Frequency of response	x	Hours per response	=	Burden hours
Information Collections	45,550		Varies		.50		336,550

Total Estimated Burden Hours: 336,550.

Status: Reinstatement with changes.

Contact: Rose Donnelly/Art Orton, HUD, (202) 708–4767; Joseph F. Lackey, Jr., OMB, (202) 395–7316.

Dated: June 25, 1996.

[FR Doc. 96–17367 Filed 7–8–96; 8:45 am]

BILLING CODE 4210–01–M

[Docket No. FR–4086–N–02]

Office of Administration; Submission for OMB Review: Comment Request

AGENCY: Office of Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due date: August 8, 1996.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within thirty (30) days from the date of this Notice. Comments should refer to the proposal by name and/or OMB approval number should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Kay F. Weaver, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 708–0050. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Ms. Weaver.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

The Notice lists the following information: (1) the title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: June 21, 1996.

David S. Cristy,

Acting Director, Information Resources Management Policy and Management Division.

Title of Proposal: Title I Property Improvement and Manufactured Home Loans.

Office: Housing.

OMB Approval Number: 2502–0328.

Description of the Need for the Information and Its Proposed Use: Title I loans are made by private lenders, and HUD insures the lender against loss from borrower defaults. The information collections are needed by HUD to evaluate program and individual lender performance and to determine whether claims are eligible for payment.

Form Number: HUD–637, 27029, 27030, 55013, 55014, 56001, 56001–MH, 56004, and 92802.

Respondents: Individuals or households and business or other for-profit.

Frequency of Submission: On occasion.

Reporting Burden:

	Number of respondents	x	Frequency of response	x	Hours per response	=	Burden hours
Information Collection	445,525		varies		varies		156,897

Total Estimated Burden Hours: 156,897.

Status: Reinstatement with changes.

Contact: Robert Coyle, HUD, (202) 755–7400 x103, Joseph F. Lackey, Jr., OMB, (202) 395–7316.

Dated: June 21, 1996.

[FR Doc. 96–17368 Filed 7–8–96; 8:45 am]

BILLING CODE 4210–01–M

[Docket No. FR–4086–N–03]

Office of Administration; Submission for OMB Review: Comment Request

AGENCY: Office of Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due date: August 8, 1996.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within thirty (30) days from the date of this Notice. Comments should refer to the proposal by name and/or OMB approval number and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Kay F. Weaver, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 708–0050. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Ms. Weaver.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: June 21, 1996.

David S. Cristy,

Acting Director, Information Resources, Management Policy and Management Division.

Title of Proposal: HUD Conditional Commitment/Direct Endorsement Statement of Appraised Value.

Office: Housing.

OMB Approval Number: 2502–0494.

Description of the Need for the Information and its Proposed Use: The form is used by HUD and HUD approved lenders. This form puts forth the value, terms and conditions of a property for mortgage insurance purposes and is mandatory for Housing Programs.

Form Number: HUD–92800.5B.

Respondents: Business or other for-profit and the Federal Government.

Frequency of Submission: On occasion.

Reporting Burden:

	Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
HUD–92800.5B	1,200,000		1		.14		168,000

Total Estimated Burden Hours: 168,000.

Status: Reinstatement without changes.

Contact: David Dwyer, HUD, (202) 708–2121; Joseph F. Lackey, Jr., OMB, (202) 395–7316.

Dated: June 21, 1996.

[FR Doc. 96–17369 Filed 7–8–96; 8:45 am]

BILLING CODE 4210–01–M

[Docket No. FR–4086–N–04]

Office of Administration; Submission for OMB Review: Comment Request

AGENCY: Office of Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due date: August 8, 1996.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within thirty (30) days from the date of this Notice. Comments should refer to the proposal by name and/or OMB approval number should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Kay F. Weaver, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 708–0050. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Ms. Weaver.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

The Notice lists the following information: (1) the title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: June 21, 1996.

David S. Cristy,

Acting Director, Information Resources Management Policy and Management Division.

Title of Proposal: Survey of Market Absorption of New Apartment Buildings (SOMA).

Office: Policy Development and Research.

OMB Approval Number: 2528–0013.

Description of the Need for the Information and its Proposed Use: The survey measures the rate at which different types of new rental and condominium apartments are absorbed, i.e., taken off the market. It provides a basis for analyzing the degree to which apartment building activity is meeting present and future needs.

Form Number: H–31 and SOMA–1.

Respondents: Business or other for-profit.

Frequency of Submission: On occasion and quarterly.

Reporting Burden:

	Number of respondents	x	Frequency of response	x	Hours per response	=	Burden hours
Information Collection	12,000		1		.3		3,600

Total Estimated Burden Hours: 3,600.

Status: Extension without changes.

Contact: Ronald J. Sepanik, HUD, (202) 708–1060 ×134 Joseph F. Lackey, Jr., OMB, (202) 395–7316.

Dated: June 21, 1996.

[FR Doc. 96–17370 Filed 7–8–96; 8:45 am]

BILLING CODE 4210–01–M

[Docket No. FR–4086–N–05]

Office of Administration; Submission for OMB Review: Comment Request

AGENCY: Office of Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments due date:* August 8, 1996.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within thirty (30) days from the date of this Notice. Comments should refer to the proposal by name and/or OMB approval number should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Kay F. Weaver, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410, telephone (202) 708–0050. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Ms. Weaver.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: June 25, 1996.

David S. Cristy,

Acting Director, Information Resources Management Policy and Management Division.

Title of Proposal: Information Request to owners of HUD-assisted Multifamily Housing in Boston, pursuant to Section III.A of Consent Decree in *NAACP, Boston Chapter* v. *Cisneros.*

Office: General Counsel.

OMB Approval Number: 2510–0008.

Description of the Need for the Information and its Proposd Use: Pursuant to Section III.A of the Consent Decree in NAACP, Boston Chapter v. *Cisneros,* HUD is required to submit semi-annual reports to the Court setting forth the current racial makeup, family composition, and vacancy rate of HUD-assisted multifamily rental housing located in the City of Boston. The information collection is required in order to prepare these reports. The reports are used to determine if there has been any progress toward achieving the goals of the Consent Decree. Respondents are owners and managers of HUD-assisted housing.

Form Number: HUD–23001.

Respondents: Business for other for-profit and not-for-profit institutions.

Frequency of Submission: Semi-annually.

Reporting Burden:

	Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
Information collection	213		2		1		426

Total Estimated Burden Hours: 426.

Status: Extension without changes.

Contact: Linda G. Katz, HUD, (617) 565–5126; Joseph F. Lackey, Jr., OMB, (202) 395–7316.

Dated: June 25, 1996.

[FR Doc. 96–17371 Filed 7–8–96; 8:45 am]

BILLING CODE 4210–01–M

[Docket No. FR–4086–N–06]

Office of Administration; Submission for OMB Review: Comment Request

AGENCY: Office of Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due date: August 8, 1996.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within thirty (30) days from the date of this Notice. Comments should refer to the proposal by name and/or OMB approval number should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Kay F. Weaver, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 708–0050. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Ms. Weaver.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

The Notice lists the following information: (1) the title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: June 25, 1996.

David S. Cristy,

Acting Director, Information Resources Management Policy and Management Division.

Title of Proposal: Request for Credit Approval of a Substitute Mortgagor.

Office: Housing.

OMB Approval Number: 2502–0036.

Description of the Need for the Inoformation and its Proposed Use: Form

HUD–92210 is an application form to approve the credit of a substitute mortgagor who desires to assume an insured mortgage loan. The form will also be used as a notification to document the file that the substitute mortgage is financially accepted.

Form Number: HUD–92210.

Respondents: Individuals or households.

Frequency of Submission: On occasion.

Reporting Burden:

	Number of respondents	x	Freqency of response	x	Hours per response	=	Burden hours
HUD–92210	1,000		10		1		10,000

Total Estimated Burden Hours: 10,000.

Status: Reinstatement without changes.

Contact: Katherine Winbach, HUD, (202) 708–1719 Joseph F.Lackey, Jr., OMB, (202) 395–7316.

Dated: June 25, 1996.

[FR Doc. 96–17372 Filed 7–8–96; 8:45 am]

BILLING CODE 4210–01–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Notice of Availability of Petition Management Guidance for Petitions Received Under the Endangered Species Act

AGENCY: Fish and Wildlife Service, Interior, and National Marine Fisheries Service. National Oceanic and Atmospheric Administration Commerce.

ACTION: Notice of document availability.

SUMMARY: The Fish and Wildlife Service and National Marine Fisheries Service (Services) announce the availability of Petition Management Guidance. This document provides internal guidance for the management of petitions submitted to the Fish and Wildlife Service and the National Marine Fisheries Service under the Endangered Species Act of 1973, as amended (Act). Its purpose is to provide policy and guidance for managing petitions to promote efficiency and nationwide consistency within the Services. The Services previously sought public comment on a draft of this guidance document.

DATES: The guidance became effective on June 25, 1996.

ADDRESSES: Persons wishing a copy of the Petition Management Guidance may obtain a copy by contacting the Division of Endangered Species, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 452, Arlington, Virginia 22203 or the Division of Endangered Species, U.S. National Marine Fisheries Service, 1335 East-West Highway, Silver Spring, Maryland 20910.

FOR FURTHER INFORMATION CONTACT: E. LaVerne Smith, Chief, Division of Endangered Species, U.S. Fish and Wildlife Service, at the above address (703/358–2171), or Robert Ziobro, Acting Chief, Division of Endangered Species, U.S. National Marine Fisheries Service, at the above address (301/703–1401).

SUPPLEMENTARY INFORMATION:

Background

Section 4(b) of the Act allows any interested individual to petition the Services to list, delist, or reclassify species, or to revise a listed species' critical habitat. The Petition Management Guidance provides specific guidance for the Services on petition identification, data/information submission standards, lead Region responsibilities, time frames for internal review of 90-day and 12-month findings, petition tracking, preparation of administrative findings and notices, and petitioner notification. The guidance differentiates among petitions requesting (1) actions petitionable under the provisions of section 4(b)(3) of the Endangered Species Act. (2) actions encompassed by other provisions of the Endangered Species Act, and (3) actions petitionable only under the Administrative Procedure Act.

The Petition Management Guidance identifies three petition categories under section 4(b)(3) of the Act as follows:

(1) Petitions to list species,

(2) Petitions to reclassify or delist species, and

(3) Petitions to revise critical habitat.

Under each of these three categories, situations are described to assist Service employees and ensure consistency in the determination of 90-day and 12-month petition findings.

Ultimately, the Services intend to ensure that the petition process serves its function by calling appropriate attention to situations affecting the welfare of species or of any other change in biological status of species that would justify rulemaking under section 4 of the Act. In this manner, the petition process will operate consistently with the Services' own listing priority systems.

Public Comments

The Services made available a draft of the petition management guidance through a notice published in the Federal Register on December 21, 1994 (59 FR 65781). Comments received in response to that notice have been considered in formulating the final guidance document.

Author/Editor

The editors of the final document are Dr. John J. Fay, U.S. Fish and Wildlife Service, Division of Endangered Species (see **ADDRESSES** section) and Marta Nammack, U.S. National Marine Fisheries Service, Division of Endangered Species (see **ADDRESSES** section).

Authority: The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: June 25, 1996.

John G. Rogers,

Director, Fish and Wildlife Service.

Dated: June 24, 1996.

Gary Matlock,

Acting Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 96–17221 Filed 7–8–96; 8:45 am]

BILLING CODE 4310–55–M

Application for Incidental Take Permit for American Burying Beetle, etc.; McCurtain County, OK

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of Receipt of Application for Incidental Take Permit for Surveying the Species Listed Below for the McCurtain County Wilderness area in Oklahoma.

APPLICANT: Greg Duffy, Oklahoma City, Oklahoma.

SUMMARY: Greg Duffy has applied to the Fish and Wildlife Service (Service) for an incidental take permit pursuant to

Section 10(A)(1)(a) of the Endangered Species Act, for the purpose of scientific research and enhancement of propagation and survival of the species as prescribed by Service recovery documents. The applicant has been assigned permit number PRT–814829. The requested permit, which is for a period of 2 years, would authorize incidental take of the following endangered species:

1. American burying beetle (Nicrophorus americanus)
2. Bald eagle (Haliaeetus leucocephalus)
3. Interior least tern (Sterna antillarum)
4. Red-cockaded woodpecker (Picoides borealis)

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. The request must be received by the Assistant Regional Director within 30 days of the date of this publication. Please refer to permit number PRT–814829 when submitting comments.

Documents and other information submitted with this application are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to the above office within 30 days of the date of publication of this notice.

Lynn B. Starnes,

Acting Regional Director, Region 2, Albuquerque, New Mexico.

[FR Doc. 96–17391 Filed 7–8–96; 8:45 am]

BILLING CODE 4510–55–P

Application for Incidental Take Permit for Mexican Spotted Owl; Coconino and Apache-Sitgreaves National Forests, AZ

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of Receipt of Application for Incidental Take Permit for Surveying the Species Listed Below for the Coconino and Apache-Sitgreaves National Forests in Arizona.

APPLICANT: Dr. Joseph L. Ganey, Flagstaff, Arizona.

SUMMARY: Dr. Joseph L. Ganey has applied to the Fish and Wildlife Service (Service) for an incidental take permit pursuant to Section 10(A)1(a) of the Endangered Species Act, for the purpose of scientific research and enhancement of propogation and survival of the species as prescribed by Service recovery documents. The applicant has been assigned permit number PRT–814833. The requested permit, which is for a period of 2 years, would authorize incidental take of the Mexican spotted owl (*Strix occidentalis lucida*).

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. The request must be received by the Assistant Regional Director within 30 days of the date of this publication. Please refer to permit number PRT–814833 when submitting comments.

Documents and other information submitted with this application are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to the above office within 30 days of the date of publication of this notice.

Lynn B. Starnes,

Acting Regional Director, Region 2, Albuquerque, New Mexico.

[FR Doc. 96–17392 Filed 7–8–96; 8:45 am]

BILLING CODE 4510–55–P

Application for Incidental Take Permit for Tessu Long-Nosed Bats, etc.; Hidalgo County, NM, et al.

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of Receipt of Application for Incidental Take Permit for Surveying the Species Listed Below at Previously Undocumented Locations including Hidalgo County, New Mexico (Peloncillo and Animas Mountains) and Cochise County, Arizona.

APPLICANT: Andrew T. Holycross, Tempe, Arizona.

SUMMARY: Andrew T. Holycross has applied to the Fish and Wildlife Service (Service) for an incidental take permit pursuant to Section 10(A)1(a) of the Endangered Species Act, for the purpose of scientific research and enhancement of propogation and survival of the species as prescribed by Service recovery documents. The applicant has been assigned permit number PRT–814837. The requested permit, which is for a period of 2 years, would authorize incidental take of the following endangered species:

1. Lesser Long-nosed bats (*Leptonycteris curasoae yerbabuena*).
2. New Mexico ridge-nosed rattlesnakes (*Crotalus willardi obscurus*).

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. The request must be received by the Assistant Regional Director within 30 days of the date of this publication. Please refer to permit number PRT–814837 when submitting comments.

Documents and other information submitted with this application are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to the above office within 30 days of the date of publication of this notice.

Lynn B. Starnes,

Acting Regional Director, Region 2, Albuquerque, New Mexico.

[FR Doc. 96–17393 Filed 7–8–96; 8:45 am]

BILLING CODE 4510–55–P

Application for Incidental Take Permit for Sacramento Mountain Thistle; Otero County, NM, et al.

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of Receipt of Application for Incidental Take Permit for Surveying the Species Listed Below for Otero County, New Mexico; Brewster County, Texas (to include Big Bend National Park and the Terlingua Creek Area); Cochise County, Arizona (San Bernadino Valley); Pima County, Arizona, and Marathon, Texas.

APPLICANT: Carolyn O'Malley, Phoenix, Arizona.

SUMMARY: Carolyn O'Malley has applied to the Fish and Wildlife Service (Service) for an incidental take permit pursuant to Section 10(A)1(a) of the Endangered Species Act, for the purpose of scientific research and enhancement of propagation and survival of the species as prescribed by Service recovery documents. The applicant has been assigned permit number PRT–814841. The requested permit, which is for a period of 2 years, would authorize incidental take of the following endangered species:

1. Sacramento Mountain thistle (*Cirsium vinaceum*)
2. Nichol's Turk's head cactus (*Echinocereus horizonthalonius v. nicholii*)
3. Davis' green pitaya (*Echinocereus viridflorus v. davisii*)
4. bunched cory cactus (*Coryphantha ramillosa*)
5. Terlingua Creek cat's eye (*Cryptantha crassipes*)
6. Sacramento prickly poppy (*Argemone pleicantha ssp. pinnatisecta*)
7. Cochise pincushion cactus (*Coryphantha robbinsorum*)

8. Lloyd's mariposa cactus (*Neolloydia mariposensis*)

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. The request must be received by the Assistant Regional Director within 30 days of the date of this publication. Please refer to permit number PRT–814841 when submitting comments.

Documents and other information submitted with this application are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to the above office within 30 days of the date of publication of this notice.

Lynn B. Starnes,

Acting Regional Director, Region 2, Albuquerque, New Mexico.

[FR Doc. 96–17394 Filed 7–8–96; 8:45 am]

BILLING CODE 4510–55–P

Application for Incidental Take Permit for Pecos Gambusia, etc.; Texas

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of Receipt of Application for Incidental Take Permit for Surveying the Species Listed Below within the State of Texas.

APPLICANT: Andrew Sansom, Austin, Texas.

SUMMARY: Andrew Sansom has applied to the Fish and Wildlife Service (Service) for an incidental take permit pursuant to Section 10(A)1(a) of the Endangered Species Act, for the purpose of scientific research and enhancement of propogation and survival of the species as prescribed by Service recovery documents. The applicant has been assigned permit number PRT–814933. The requested permit, which is for a period of 2 years, would authorize incidental take of the following endangered species:

1. Pecos gambusia (*Gambusia nobilis*)
2. Houston toad (*Bufo Houstonensis*)
3. Golden-cheeked warbler (*Dendroica chrysoparia*)
4. Red-cockaded woodpecker (*Picoides borealis*)
5. Louisiana black bear (*Ursus americanus luteolus*)
6. Ocelot (*Felis pardalis*)
7. Jaguarundi (*Felis yagouaroundi cacomitli*)
8. One flowering plant within the State

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. The request must be received by the Assistant Regional Director within 30 days of the date of this publication. Please refer to permit number PRT–814933 when submitting comments.

Documents and other information submitted with this application are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to the above office within 30 days of the date of publication of this notice.

Lynn B. Starnes,

Acting Regional Director, Region 2, Albuquerque, New Mexico.

[FR Doc. 96–17395 Filed 7–8–96; 8:45 am]

BILLING CODE 4510–55–P

Application for Incidental Take Permit for Fountain Darter, etc.; San Marcos National Fish Hatchery and Technology Center, TX

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of Receipt of Application for Incidental Take Permit for Surveying the Species Listed Below from San Marcos National Fish Hatchery and Technology Center.

APPLICANT: William M. Seawell, San Marcos, Texas.

SUMMARY: William M. Seawell has applied to the Fish and Wildlife Service (Service) for an incidental take permit pursuant to Section 10(A)1(a) of the Endangered Species Act, for the purpose of scientific research and enhancement of propogation and survival of the species as prescribed by Service recovery documents. The applicant has been assigned permit number PRT–814863. The requested permit, which is for a period of 2 years, would authorize incidental take of the following endangered species:

1. Fountain darters (*Etheostoma fonticola*)
2. Texas blind salamanders (*Typhlomolge rathbuni*)
3. San Marcos Gambusia (*Gambusia georgei*)
4. Texas wild rice (*Zizania texana*)

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. The request must be received by the Assistant Regional Director within 30 days of the date of this publication. Please refer to permit number PRT–814863 when submitting comments.

Documents and other information submitted with this application are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to the above office within 30 days of the date of publication of this notice.

Lynn B. Starnes,

Acting Regional Director, Region 2, Albuquerque, New Mexico.

[FR Doc. 96–17396 Filed 7–8–96; 8:45 am]

BILLING CODE 4510–55–P

Application for Incidental Take Permit for Attwater's Greater Prairie Chicken; Colorado County et al., TX

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of Receipt of Application for Incidental Take Permit for Surveying Attwater's Greater Prairie Chicken in Colorado, Galveston, and Refugio Counties; Glen Rose, College Station, Houston, and San Antonio, Texas.

APPLICANT: Terry Rossignal, Eagle Lake, Texas.

SUMMARY: Terry Rossignal has applied to the Fish and Wildlife Service (Service) for an incidental take permit pursuant to Section 10(A)1(a) of the Endangered Species Act, for the purpose of scientific research and enhancement of propogation and survival of Attwater's greater prairie chicken (*Tympanuchus cupido attwateri*) as prescribed by Service recovery documents. The applicant has been assigned permit number PRT–814917. The requested permit, which is for a period of 2 years, would authorize incidental take of Attwater's greater prairie chicken.

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. The request must be received by the Assistant Regional Director within 30 days of the date of this publication. Please refer to permit number PRT–814917 when submitting comments.

Documents and other information submitted with this application are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to the above

office within 30 days of the date of publication of this notice.

Lynn B. Starnes,

Acting Regional Director, Region 2, Albuquerque, New Mexico.

[FR Doc. 96–17397 Filed 7–8–96; 8:45 am]

BILLING CODE 4510–55–P

Application for Incidental Take Permit for Mexican Spotted Owl, Pima County, AZ

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of Receipt of Application for Incidental Take Permit for Surveying the Mexican Spotted Owl for the Rincon Mountains, East District of Saguaro National Park, Pima County, Arizona.

APPLICANT: Dr. Charles Van Riper, Flagstaff, Arizona.

SUMMARY: Dr. Charles Van Riper has applied to the Fish and Wildlife Service for an incidental take permit pursuant to Section 10(A)1(a) of the Endangered Species Act, for the purpose of scientific research and enhancement of propogation and survival of the Mexican spotted owl (*Strix occidentalis lucida*) as prescribed by Service recovery documents. The applicant has been assigned permit number PRT–812832. The requested permit, which is for a period of 1 year, would authorize incidental take of the species.

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. The request must be received by the Assistant Regional Director within 30 days of the date of this publication. Please refer to permit number PRT–812832 when submitting comments.

Documents and other information submitted with this application are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to the above office within 30 days of the date of publication of this notice.

Lynn B. Starnes,

Acting Regional Director, Region 2, Albuquerque, New Mexico.

[FR Doc. 96–17398 Filed 7–8–96; 8:45 am]

BILLING CODE 4510–55–P

Bureau of Indian Affairs

Indian Gaming

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of Amendment to 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) gambling on Indian reservations. The Assistant Secretary—Indian Affairs, Department of the Interior, through her delegated authority, has approved the Amendment to the Tribal-State Compact Between the Eastern Band of Cherokee Indians and the State of North Carolina, which was executed on May 28, 1996.

DATES: This action is effective July 9, 1996.

FOR FURTHER INFORMATION CONTACT: George T. Skibine, Director, Indian Gaming Management Staff, Bureau of Indian Affairs, Washington, D.C. 20240, (202) 219–4068.

Dated: June 28, 1996.

Ada E. Deer,

Assistant Secretary—Indian Affairs.

[FR Doc. 96–17429 Filed 7–8–96; 8:45 am]

BILLING CODE 4310–02–M

Bureau of Land Management

[UT–040–06–1220–00]

Utah; Closure of Public Lands

AGENCY: Bureau of Land Management, Interior.

ACTION: Emergency Closure of Public Lands.

NOTICE: Utah, Washington County, Cedar City District Office, Dixie Resource Area.

SUMMARY: Notice is hereby given that effective immediately all public lands in the north half of Section 1, Township 42 South, Range 11 West of the Salt Lake Baseline and Meridian, including the unauthorized Slickrock Swamp Trail, are closed to mountain bike use and motorized vehicles with the exception of fire and emergency vehicles, law enforcement, government officials in the conduct of official business, and authorized permittees of the Bureau of Land Management. This closure is in accordance with the provisions of 43 CFR 8341.2.

The purpose of the closure is to protect the City of Rockville municipal watershed and to reduce soil erosion on the Rockville Bench. The fragile soils and watershed are threatened because of the creation and use of an unauthorized mountain bike trail. The closure will also curtail trespass problems that are occurring on surrounding private property as a result of mountain bike use on the trail. The closure will remain in effect until specific land use planning is completed for the parcel.

ADDRESSES: More information can be obtained from R.J. Hughes at the Dixie Resource Area, 345 E. Riverside Drive, St. George, Utah 84790, (801) 673–4654.

Dated: June 26, 1996.

G. Von Swain,

Acting District Manager, Cedar City District.

[FR Doc. 96–17435 Filed 7–8–96; 8:45 am]

BILLING CODE 4210–DQ–P–M

[OR–130–1020–00; GP6–0207]

Cancellation of Meetings of the Interior Columbia Basin Ecosystem Management Project Subgroup of the Eastern Washington Resource Advisory Council; and of the Eastern Washington Resource Advisory Council

AGENCY: Bureau of Land Management, Spokane District.

ACTION: Cancellation of meetings of the Interior Columbia Basin Ecosystem Management Project Subgroup of the Eastern Washington Resource Advisory Council; July 18, 1996, in Spokane, Washington; and the cancellation of the meeting of the Eastern Washington Resource Advisory Council; July 19, 1996, in Spokane, Washington.

SUMMARY: The meeting of the Interior Columbia Basin Ecosystem Management Project Subgroup of the Eastern Washington Resource Council scheduled for July 18, 1996; is cancelled. The meeting of the Eastern Washington Resource Advisory Council scheduled for July 19, 1996 is cancelled.

FOR FURTHER INFORMATION CONTACT: Richard Hubbard, Bureau of Land Management, Spokane District Office, 1103 N. Fancher Road, Spokane, Washington, 99212; or call 509–536–1200.

Dated: July 3, 1996.

Joseph K. Buesing,

District Manager.

[FR Doc. 96–17530 Filed 7–8–96; 8:45 am]

BILLING CODE 4310–33–P

[OR–130–1020–00; GP6–0208]

Meetings of the Interior Columbia Basin Ecosystem Management Project and the Eastern Washington Resource Advisory Council

AGENCY: Bureau of Land Management, Spokane District.

ACTION: The meeting of the Interior Columbia Basin Ecosystem Management Project Subgroup of the Eastern Washington Resource Advisory Council is scheduled for August 8, 1996, in Spokane, Washington. The meeting of the Eastern Washington Resource Advisory Council is scheduled August 9, 1996, in Spokane, Washington.

SUMMARY: The meeting of the Interior Columbia Basin Ecosystem Management Project Subgroup of the Eastern Washington Resource Advisory Council August 8, 1996, will convene at 9:00 a.m., at the Bureau of Land Management, Spokane District Office, 1103 N. Fancher Road, Spokane, Washington, 99212–1275. The meeting will adjourn at approximately 4:00 p.m. or upon completion of business. At an appropriate time, the meeting will recess for approximately one hour for lunch. Public comments will be received from 10:00 a.m. until 10:30 a.m. The purpose of the Interior Columbia Basin Ecosystem Management Project (ICBEMP) Subgroup meeting is to discuss ICBEMP Alternatives.

A meeting of the Eastern Washington Resource Advisory Council will be held on August 9, 1996. The meeting will convene at 9:00 a.m. at The Red Lion Inn, South ''C'' Ballroom, N. 322 Spokane Falls Ct., Spokane, Washington, 99201; (509) 455–9600. The meeting will adjourn upon completion of business, but no later than 4:00 p.m. At an appropriate time, the meeting will recess for approximately one hour for lunch.

Public comments will be received from 10:00 a.m. until 10:30 a.m. The purpose of meeting is to address the Interior Columbia Basin Ecosystem Management Project and to address for Standards for Rangeland Health and Livestock Grazing Guidelines.

FOR FURTHER INFORMATION CONTACT: Richard Hubbard, Bureau of Land Management, Spokane District Office, 1103 N. Fancher Road, Spokane, Washington, 99212; or call 509–536–1200.

Dated: July 3, 1996.

Joseph K. Buesing,

District Manager.

[FR Doc. 96–17531 Filed 7–8–96; 8:45 am]

BILLING CODE 4310–33–P

[MT–924–1430–01; NDM 83168]

Public Land Order No. 7206; Withdrawal of Public Lands for Waterfowl Production Areas; North Dakota

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order withdraws 1,108.60 acres of public lands from surface entry and mining for a period of 50 years for the Fish and Wildlife Service to protect waterfowl production areas. The lands have been and will remain open to mineral leasing.

EFFECTIVE DATE: July 9, 1996.

FOR FURTHER INFORMATION CONTACT: Dick Thompson, BLM Montana State Office, P.O. Box 36800, Billings, Montana 59107, 406–255–2829.

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1988), it is ordered as follows:

1. Subject to valid existing rights, the following described public lands are hereby withdrawn from settlement, sale, location, or entry under the general land laws, including the United States mining laws (30 U.S.C. Ch. 2 (1988)), but not from leasing under the mineral leasing laws, to protect waterfowl production areas:

Fifth Principal Meridian

T. 130 N., R. 68 W.,
  Sec. 24, lot 6, SW¼NE¼, and NW¼SE¼.
T. 132 N., R. 68 W.,
  Sec. 20, NE¼NE¼.
T. 135 N., R. 69 W.,
  Sec. 28. N½NE¼.
T. 135 N., R. 70 W.,
  Sec. 8, NE¼SW¼SW¼SW¼.
T. 141 N., R. 81 W.,
  Sec. 26, lots 1 and 2, NE¼SE¼, and SW¼SE¼.
T. 142 N., R. 75 W.,
  Sec. 12, S½SW¼;
  Sec. 14, S½SW¼ and E¼SE¼;
  Sec. 22, N½NE¼;
  Sec. 26, NW¼NE¼ and NE¼NW¼.
T. 143 N., R. 81 W.,
  Sec. 6, lots 1 and 2;
  Sec. 18, lot 3.
T. 144 N., R. 83 W.,
  Sec. 30, lot 4.
T. 144 N., R. 84 W.,
  Sec. 8, lots 1, 2, and 3.
T. 145 N., R. 84 W.,
  Sec. 34, lots 3 and 4.
T. 146 N., R. 84 W.,
  Sec. 32, lots 1, 4, 5, and 8.
T. 153 N., R. 75 W.,
  Sec. 31, lots 2 and 4.

The areas described aggregate 1,108.60 acres in Burleigh, Logan, McHenry, McIntosh, and McLean Counties.

2. The withdrawal made by this order does not alter the applicability of those public land laws governing the use of lands under lease, license, or permit, or governing the disposal of their mineral or vegetative resources other than under the mining law.

3. This withdrawal will expire 50 years from the effective date of this order unless, as a result of a review conducted before the expiration date pursuant to Section 204(f) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(f) (1988), the Secretary determines that the withdrawal shall be extended.

Dated: June 24, 1996.

Bob Armstrong,

Assistant Secretary of the Interior.

[FR Doc. 96–17341 Filed 7–8–96; 8:45 am]

BILLING CODE 4310–DN–P

[AZ–942–06–1420–00]

Arizona; Notice of Filing of Plats of Survey

Date: July 1, 1996.

1. The plats of survey of the following described lands were officially filed in the Arizona State Office, Phoenix, Arizona, on the dates indicated:

A plat representing the dependent resurvey of a portion of the subdivisional lines, the subdivision of section 17, and a metes-and-bounds survey, in Township 1 North, Range 4 East, Gila and Salt River Meridian, Arizona, was approved April, 1996, and officially filed April 18, 1996.

A supplemental plat showing amended lottings of fractional areas created by the segregation of patented mineral surveys and the cancellation of Mineral Surveys 1909, 2242, 3167, and 3236, in section 10, Township 23 South, Range 24 East, Gila and Salt River Meridian, Arizona, was approved April 29, 1996, and officially filed May 7, 1996.

A supplemental plat showing amended lottings of fractional areas created by the segregation of patented mineral surveys and the cancellation of Mineral Survey 2555, Section 11, Township 23 South Range 24 East, Gila and Salt River Meridian, Arizona, was approved April 29, 1996, and officially filed May 7, 1996.

A plat, in 3 sheets, representing the dependent resurvey of a portion of the subdivisional lines, and the subdivision of sections 22 and 27, the metes-and-bounds surveys of Tracts 37, 38 and 39, and the segregation of unpatented Mineral Survey No. 4722, Township 4 South, Range 15 East, Gila and Salt River Meridian, Arizona, was approved May 6, 1996, and officially filed May 9, 1996.

A plat representing the dependent resurvey of a portion of the Fifth Guide Meridian East (east boundary), the subdivision of section 12, a metes-and-bounds survey in section 12 and an Informative Traverse of the Right Bank of the San Francisco River in Section 12, Township 5 South, Range 29 East, Gila and Salt River Meridian, Arizona, was approved May 13, 1996, and officially filed May 21, 1996.

A plat representing the dependent resurvey of a portion of the west boundary, a portion of the subdivisional lines; and metes-and-bounds surveys in Sections 19 and 30, Township 14 North, Range 11 West, Gila and Salt River Meridian, Arizona, was approved June 26, 1996, and officially filed July 3, 1996.

2. These plats will immediately become the basic records for describing the land for all authorized purposes. These plats have been placed in the open files and are available to the public for information only.

3. All inquiries relating to these lands should be sent to the Arizona State Office, Bureau of Land Management, P.O. Box 16563, Phoenix, Arizona 85011.

Dennis K. McKay,

Acting Chief Cadastral Surveyor of Arizona.

[FR Doc. 96–17399 Filed 7–8–96; 8:45 am]

BILLING CODE 4310–31–M

[ES–960–1420–00; ES–48108, Group 29, Missouri]

Notice of Filing of Plat of Survey; Missouri

The plat of the dependent resurvey of the north, east, and west boundaries; a portion of the south boundary, and a portion of the subdivisional lines, and the subdivision of certain sections, Township 32 North, Range 5 East, Fifth Principal Meridian, Missouri, will be officially filed in Eastern States, Springfield, Virginia at 7:30 a.m., August 12, 1996.

The survey was requested by the U.S. Forest Service.

All inquiries or protests concerning the technical aspects of the survey must be sent to the Chief Cadastral Surveyor, Eastern States, Bureau of Land Management, 7450 Boston Boulevard, Springfield, Virginia 22153, prior to 7:30 a.m., August 12, 1996.

Copies of the plat will be made available upon request and prepayment of the reproduction fee of $2.75 per copy.

Dated: June 27, 1996.

Stephen G. Kopach,

Chief Cadastral Surveyor.

[FR Doc. 96–17340 Filed 7–8–96; 8:45 am]

BILLING CODE 4310–GS–M

National Park Service

Acadia National Park Bar Harbor, MA; Acadia National Park Advisory Commission; Notice of Meeting

Notice is hereby given in accordance with the Federal Advisory Committee Act (Public Law 92–463, 86 Stat. 770, 5 U.S.C. Ap. 1, Sec. 10), that the Acadia National Park Advisory Commission will hold a meeting on Monday, August 5, 1996.

The Commission was established pursuant to Public Law 99–420, Sec. 103. The purpose of the commission is to consult with the Secretary of the Interior, or his designee, on matters relating to the management and development of the park, including but not limited to the acquisition of lands and interests in lands (including conservation easements on islands) and termination of rights of use and occupancy.

The meeting will convene at park headquarters, Acadia National Park, Rt. 233, Bar Harbor, Maine, at 1:00 p.m. to consider the following agenda:

1. Review and approval of minutes from the meeting held May 13, 1996.
2. Report of the following subcommittees:
   A. Conservation Easement
   B. Acquisition
   C. Planning
3. Bylaw changes.
4. Superintendent's report: Tour of park facilities; i.e., carriage roads, gatehouse exteriors, Jordan Pond House and trails.
5. Public comments.
6. Proposed agenda and date of next Commission meeting to be held jointly with Friends of Acadia leaders and Board, and League of Towns members.

The meeting is open to the public. Interested persons may make oral/written presentations to the Commission or file written statements. Such requests should be made to the Superintendent at least seven days prior to the meeting to: Superintendent, Acadia National Park, P.O. Box 177, Bar Harbor, Maine 04609–0177, tel: (207) 288–3338.

Dated: June 26, 1996.

Paul F. Haertel,

Superintendent, Acadia National Park.

[FR Doc. 96–17424 Filed 7–8–96; 8:45 am]

BILLING CODE 4310–70–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–748 (Preliminary)]

Engineered Process Gas Turbo-Compressor Systems From Japan

Determination

On the basis of the record [1] developed in the subject investigation, the Commission determines, pursuant to section 733(a) of the Tariff Act of 1930 (19 U.S.C. § 1673b(a)), that there is a reasonable indication that an industry in the United States is threatened with material injury by reason of imports from Japan of engineered process gas turbo-compressor systems, provided for in subheadings 8414.80.20, 8419.60.50, 8414.90.40, 8406.81.10, 8406.82.10, 8406.90.20 through 8406.90.45, 9032.89.60, 8501.53.40, 8501.53.60, 8501.53.80, and 8483.40.50, of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value (LTFV).

Background

On May 8, 1996, a petition was filed with the Commission and the Department of Commerce by Dresser-Rand Co., Corning, NY, alleging that an industry in the United States is materially injured and threatened with material injury by reason of LTFV imports of engineered process gas turbo-compressor systems from Japan. Accordingly, effective May 8, 1996, the Commission instituted antidumping investigation No. 731–TA–748 (Preliminary). On May 24, 1996, The United Steelworkers of America (USW), Pittsburgh, PA, which represents the production workers at the petitioner's and two other U.S. producers' facilities, filed a letter with the Commission and Commerce indicating that it was joining Dresser-Rand as a co-petitioner.

Notice of the institution of the Commission's investigation and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the Federal Register of May 17, 1996 (61 FR 24952). The conference was held in Washington, DC, on May 29, 1996, and all persons who requested the opportunity were permitted to appear in person or by counsel.

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR § 207.2(f)).

The Commission transmitted its determination in this investigation to the Secretary of Commerce on June 24, 1996. The views of the Commission are contained in USITC Publication 2976 (July 1996) entitled ''Engineered Process Gas Turbo-Compressor Systems from Japan: Investigation No. 731–TA–748 (Preliminary).''

By order of the Commission.

Issued: July 1, 1996.

Donna R. Koehnke,

Secretary.

[FR Doc. 96–17427 Filed 7–8–96; 8:45 am]

BILLING CODE 7020–02–P

[Investigation No. 337–TA–372 Enforcement Proceeding]

Certain Neodymium-Iron-Boron Magnets, Magnet Alloys, and Articles Containing Same; Notice of Referral of Formal Enforcement Proceeding to an Administrative Law Judge for Issuance of a Recommended Determination

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Commission has referred the formal enforcement proceeding instituted on April 25, 1996, in the above-captioned investigation to an administrative law judge for appropriate proceedings and the issuance of a recommended determination.

FOR FURTHER INFORMATION CONTACT: Jay H. Reiziss, Esq., Office of the General Counsel, U.S. International Trade Commission, telephone 202–252–3116.

SUPPLEMENTARY INFORMATION: On October 10, 1995, the Commission issued a notice that it had determined not to review an initial determination (Order No. 29) of the presiding administrative law judge in the above-captioned investigation granting a motion to terminate the investigation as to respondents San Huan New Materials High Tech, Inc., Ningbo Konit Industries, Inc., and Tridus International, Inc. (the ''San Huan respondents'') on the basis of a Consent Order, and subsequently issued the Consent Order. The Consent Order provides that the San Huan respondents:

shall not sell for importation, import into the United States or sell in the United States after importation or knowingly aid, abet, encourage, participate in, or induce the sale for importation, importation into the United States or sale in the United States after importation of neodymium-iron-boron magnets which infringe any of claims 1–3 of the '439 patent, or articles or products which contain such magnets, except under consent or license from Crucible.

On March 4, 1996, complainant Crucible Materials Corporation filed a complaint alleging that the San Huan respondents had violated the Consent Order and seeking institution of a formal enforcement proceeding. Crucible requested that the Commission enforce the Consent Order, impose civil penalties, assess reasonable attorney's fees, and impose such other remedies and sanctions as are appropriate. On March 12 and 28, 1996, the San Huan respondents filed letters objecting, *inter alia,* to a formal enforcement proceeding and requesting that an informal enforcement proceeding instead be instituted.

On April 25, 1996, the Commission issued an Order instituting a formal enforcement proceeding and instructing the Secretary to transmit the enforcement proceeding complaint to the San Huan respondents through counsel for a response. On June 4, 1996, the San Huan respondents filed a response to the complaint, denying violation of the Consent Order and infringement of the patent claims at issue and requesting that the Commission deny all relief sought and terminate the enforcement proceeding with prejudice.

Having examined the San Huan respondents' response to the formal enforcement proceeding complaint filed by Crucible, and having found that issues concerning possible violation of the Commission's Consent Order remain, the Commission determined to refer the enforcement proceeding to Judge Paul J. Luckern for issuance of a recommended determination concerning whether San Huan New Materials High Tech, Inc., Ningbo Konit Industries, Inc., and/or Tridus International, Inc. are in violation of the Commission's Consent Order. The recommended determination is to be issued within six (6) months of the Commission Order referring the enforcement proceeding to the administrative law judge.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and section 210.75 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.75).

Copies of the Commission's Order and all other nonconfidential documents filed in connection with this enforcement proceeding are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone 202–205–2000. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810.

Issued: July 1, 1996.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 96–17426 Filed 7–8–96; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act and the Resource Conservation and Recovery Act

In accordance with Department of Justice Policy, 28 CFR 50.7, 38 FR 19029, and 42 U.S.C. § 9622(d), notice is hereby given that on June 24, 1996, a proposed Consent Decree was lodged with the United States District Court for the Western District of Washington, *United States* v. *ASARCO Inc.*, Civil Action No. C91–5528B. The proposed Consent Decree settles claims asserted by the United States at the request of the United States Environmental Protection Agency (EPA) for releases of hazardous substances at the Asarco Smelter Operable Unit of the Commencement Bay Nearshore/Tideflats Superfund Site in Ruston and Tacoma, Washington. The defendant in the action is ASARCO Incorporated (Asarco). The claims of the United States on behalf of EPA are based upon contamination of the Asarco Smelter Site. The Asarco Smelter Site is comprised of the Asarco smelter facility, which is approximately sixty-seven acres in size, and the adjacent twenty-three acre slag peninsula.

In its amended complaint, the United States asserted claims against Asarco pursuant to Sections 106 and 107(a) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), as amended, 42 U.S.C. §§ 9606 and 9607(a), and Section 7003 of the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. § 6973, for injunctive relief to abate an imminent and substantial endangerment to public health or welfare or the environment due to the release or threatened release of hazardous substances at the Asarco Smelter Site. The United States also sought recovery of costs that have been and will be incurred in response to releases and

threatened releases of hazardous substances at the Asarco Smelter Site, and a declaration that Asarco is liable for such costs.

In the Consent Decree, Asarco agrees to implement the remedy set forth in EPA's Record of Decision (ROD) for the Asarco Smelter Site dated March 24, 1995. Asarco agrees to: (1) excavate approximately 160,000 cubic yards of soil and slag contaminated above action levels; (2) dispose of the contaminated soil and demolition debris designated as hazardous waste in an on-site containment facility (OCF) which meets or exceeds regulatory standards for hazardous waste landfills; (3) cap the entire Site with a low-permeability cap composed of layers of clean soils, gravel and clay; (4) demolish the remaining buildings and structures on the Site; (5) replace the entire surface water drainage system; (6) armor portions of the plant site and slag peninsula shoreline; (7) continue to monitor the sediments and groundwater under an Administrative Order on Consent currently in effect; and (8) develop and implement an enforceable program of restrictions and guidelines to supplement the actual cleanup activities to ensure that the remedial action remains protective and that development activities do not impact the long-term effectiveness of the cleanup. Asarco will also reimburse the United States for $3,081,510.00 in past response costs that the United States has incurred relating to the Asarco Smelter Site and will reimburse the United States for all of its future response costs at the Site.

In exchange, Asarco will receive a covenant not to sue from the United States with respect to the Asarco Smelter Site for claims pursuant to Sections 106 and 107(a) of CERCLA and Section 7003 of RCRA.

The Department of Justice will receive written comments relating to the proposed Consent Decree for thirty (30) days from the date of publication of this notice. Comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, U.S. Department of Justice, Washington, D.C. 20530, and should refer to *United States* v. *ASARCO Inc.*, D.J. Ref. No. 90–11–2–698A. Commenters may request an opportunity for a public meeting in the affected area, in accordance with Section 7003 of RCRA.

The proposed Consent Decree and exhibits may be examined at the following locations: the Region 10 Office of EPA, 7th Floor Records Center, 1200 Sixth Avenue, Seattle, WA 98101; ASARCO Information Center, 5311 North Commercial, Ruston, Washington 98407; the Tacoma Public Library, Main Branch, 1102 Tacoma Avenue South, Northwest Room, Tacoma, WA 98402; and Citizens for a Healthy Bay, 771 Broadway, Tacoma, WA 98402. The complete Administrative Record for the Asarco Smelter Site may be reviewed at the EPA Region 10 office in Seattle and at the Main Branch of the Tacoma Public Library.

A copy of the Consent Decree and exhibits (if requested) may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, N.W., 4th Floor, Washington, D.C. 20005, (202) 624–0892. In requesting copies, please enclose a check in the amount of $22.75 (without exhibits) or $297.00 (with exhibits) (25 cents per page reproduction cost) payable to the ''Consent Decree Library.''

Bruce Gelber,

Deputy Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 96–17311 Filed 7–8–96; 8:45 am]

BILLING CODE 4410–01–M

Drug Enforcement Administration

Importation of Controlled Substances; Notice of Application

Pursuant to Section 1008 of the Controlled Substances Import and Export Act (21 U.S.C. 958(i)), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in Schedule I or II and prior to issuing a regulation under Section 1002(a) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with Section 1311.42 of Title 21, Code of Federal Regulations (CFR), notice is hereby given that on February 23, 1996, Med-Pharmex Inc., 2727 Thompson Creek Road, Pomona, California 91767, made application to the Drug Enforcement Administration to be registered as an importer of pentobarbital (2270) a basic class of controlled substance listed Schedule II.

The firm plans to import pentobarbital to manufacture an euthanasia product for animals.

Any manufacturer holding, or applying for, registration as a bulk manufacturer of this basic class of controlled substance may file written comments on or objections to the application described above and may, at the same time, file a written request for a hearing on such application in accordance with 21 CFR 1301.54 in such form as prescribed by 21 CFR 1316.47.

Any such comments or objections may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, D.C. 20537, Attention: DEA Federal Register Representative (CCR), and must be filed no later than August 8, 1996.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1311.42 (b), (c), (d), (e), and (f). As noted in a previous notice at 40 FR 43745–46 (September 23, 1975), all applicants for registration to import a basic class of any controlled substance in Schedule I or II are and will continue to be required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1311.42 (a), (b), (c), (d), (e), and (f) are satisfied.

Dated: July 1, 1996.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 96–17337 Filed 7–8–96; 8:45 am]

BILLING CODE 4410–09–M

Immigration and Naturalization Service

Agency Information Collection Activities: Revision of Existing Collection; Comment Request

ACTION: Notice of Information Collection Under Review; Guam Visa Waiver Information.

The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for ''sixty days'' from the date listed at the top of this page in the Federal Register.

Request written comments and suggestions from the public and affected agencies concerning the proposed collection of information. Your comments should address one or more of the following four points:

(1) evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) enhance the quality, utility, and clarity of the information to be collected; and

(4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–616–7600, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 5307, 425 I Street, NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the items(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

Overview of this information collection.

(1) Type of Information Collection: *Revision of a currently approved collection.*

(2) Title of the Form/Collection: Guam Visa Waiver Information.

(3) Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection: Form I–736. Office of Examinations, Inspections Division, Immigration and Naturalization Service.

(4) Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Individuals or households, and business or other for-profit. The information collection is used to record an alien's application for a waiver of the non-immigrant visa requirement for entry into Guam in compliance with 8 CFR 212.1(e).

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: 170,000 responses at 5 minutes (.083) per response.

(6) An estimate of the total public burden (in hours) associated with the collection: 14,110 annual burden hours.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street NW., Washington, DC 20530.

Dated: July 2, 1996.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 96–17313 Filed 7–8–96; 8:45 am]

BILLING CODE 4410–18–M

Immigration and Naturalization Service

Agency Information Collection Activities: Extension of Existing Collection; Comment Request

ACTION: Notice of Information Collection Under Review; Application to Replace Alien Registration Card.

Office of Management and Budget (OMB) approval is being sought for the information collection listed below. This proposed information collection was previously published in the Federal Register on April 22, 1996, at 61 FR 17728–17729, allowing for a 60-day public comment period. No comments were received by the Immigration and Naturalization Service.

The purpose of this notice is to allow an additional 30 days for public comments from the date listed at the top of this page in the Federal Register. This process is conducted in accordance with 5 CFR Part 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC, 20530. Additionally, comments may be submitted to OMB via facsimile to 202–395–7285. Comments may also be submitted to the Department of Justice (DOJ), Justice Management Division, Information Management and Security Staff, Attention: Department Clearance Officer, Suite 850, 1001 G Street, NW, Washington, DC 20530. Additionally, comments may be submitted to DOJ via facsimile to 202–514–1534.

Written comments and suggestions from the public and affected agencies should address one or more of the following points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. The proposed collection is listed below:

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection.* Application to Replace Alien Registration Card.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form I–90. Office of Examinations, Adjudications, Immigration and Naturalization Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or Households. The information collected will be used by the INS to determine eligibility for an initial Alien Registration Card, or to Replace a previously issued card.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 1,300,000 responses at 55 minutes (.90) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 1,170,000 annual burden hours.

Public comment on this proposed information collection is strongly encouraged.

Dated: July 2, 1996.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 96–17312 Filed 7–8–96; 8:45 am]

BILLING CODE 4410–18–M

Office of Juvenile Justice and Delinquency Prevention

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of Information Collection Under Review; Juveniles Taken Into Custody Reporting Program.

Office of Management and Budget (OMB) approval is being sought for the

information collection listed below. This proposed information collection was previously published in the Federal Register and allowed 60 days for public comment.

The purpose of this notice is to allow an additional 30 days for public comments from the date listed at the top of this page in the Federal Register. This process is conducted in accordance with 5 Code of Federal Regulations, Part 1320.10. Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to 202–395–7285. Comments may also be submitted to the Department of Justice (DOJ), Justice Management Division, Information Management and Security Staff, Attention: Department Clearance Officer, Suite 850, 1001 G Street, NW, Washington, DC 20530. Additionally, comments may be submitted to DOJ via facsimile to 202–514–1534. Written comments and suggestions from the public and affected agencies should address one or more of the following points:

(1) evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) evaluate the accuracy of the agencies/components estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) enhance the quality, utility, and clarity of the information to be collected; and

(4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) Type of information collection: Revision of a currently approved collection.

(2) The title of the form/collection: Edward Byrne Memorial State and Local Law Enforcement Assistance Program.

(3) The agency form number, if any, and the applicable component of the Department sponsoring the collection. Form: None. Office of Juvenile Justice and Delinquency Prevention, Office of Justice Programs, United States Department of Justice.

(4) Affected public who will be asked or required to respond, as well as a brief abstract: Primary: State and Local governments. Other: None. To enumerate and describe annual movements of juvenile offenders through state correctional systems. It will be used by the Department of Justice for planning and policy affecting states. Providers of data are personnel in state departments of corrections and juvenile services.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: 51 respondents with an average 12 hours per respondent.

(6) An estimate of the total public burden (in hours) associated with the collection: 628 annual burden hours.

Public comment on this proposed information collection is strongly encouraged.

Dated: July 2, 1996.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 96–17314 Filed 7–8–96; 8:45 am]

BILLING CODE 4410–18–M

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Emergency Review, Comment Request

July 1, 1996.

The Department of Labor has submitted the following (see below) information collection request (ICR), utilizing emergency review procedures, to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (P.L. 104–13, 44 U.S.C. Chapter 35). OMB approval has been requested by July 10, 1996. A copy of this ICR, with applicable supporting documentation, may be obtained by calling the Department of Labor Acting Departmental Clearance Officer, Theresa M. O'Malley ((202) 219–5095).

Comments and questions about the ICR listed below should be forwarded to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Department of Labor, Office of Management and Budget, Room 10235, Washington, DC 20503 ((202) 395–7316).

The Office of Management and Budget is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection technique or other forms of information technology, e.g., permitting electronic submissions of responses.

Agency: Department of Labor, Bureau of International Labor Affairs.

Title: International Child Labor Study Company Questionnaire.

OMB Number: 1225-Onew.

Frequency: One time.

Affected Public: Business or other profit.

Number of Respondents: 48.

Estimated Time Per Respondent: 5 hours.

Total Burden Hours: 240.

Total Burden Cost (Capital/startup): 0.

Description: The Department of Labor (DOL) requires the requested information in order to complete a Congressionally-mandated report on international child labor (pursuant to the 1996 Omnibus Appropriations Act, P.L. 104–134). Congress has requested that DOL's report include an examination of the top 20 importers of garments, their contractors and subcontractors, and their codes of conduct and those of their contractors and subcontractors regarding the use of exploitative child labor in the production of goods imported to the United States. DOL requests that the top U.S. retailers and manufacturers furnish information regarding their garment imports and codes of conduct in order to fulfill the Congressional mandate. DOL has requested an emergency review so as to be able to provide Congress with the completed study by September 30, 1996.

Theresa M. O'Malley,

Acting Departmental Clearance Officer.

[FR Doc. 96–17374 Filed 7–8–96; 8:45 am]

BILLING CODE 4510–28–M

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance and NAFTA Transitional Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended, the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA–W) issued during the period of June, 1996.

In order for an affirmative determination to be made and a certification of eligibility to apply for worker adjustment assistance to be issued, each of the group eligibility requirements of Section 222 of the Act must be met.

(1) that a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated,

(2) that sales or production, or both, of the firm or subdivison have decreased absolutely, and

(3) that increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Negative Determinations for Worker Adjustment Assistance

In each of the following cases the investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA–W–32,220; International Paper Co., Reedsport, OR

TA–W–32,282; Karl Schmidt UNISIA, Inc., Bohn Piston, South Haven, MI

TA–W–32, 309; Cominco American, Inc., Trentwood Warehouse, Spokane, WA

TA–W–32,254; CHF Industries, New Bedford, MA

In the following cases, the investigation revealed that the criteria for eligibility have not been met for the reasons specified.

TA–W–32,389; Snapp Tool & Die, Inc., El Paso, TX

TA–W–32,280; Alstyle Apparel, Lebanon, KY

TA–W–32,455; Arco International Oil & Gas Co., Plano, TX

Increase imports did not contribute importantly to worker separations at the firm.

TA–W–32,226; Spencer Industries, Inc., Gainesville, GA

TA–W–32,338, TA–W–32,339, TA–W–32,340; Highland Aritificial Lift, Enid, OK, Oklahoma City, OK, Garden City, KS

The workers firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued; the date following the company name & location for each determination references the impact date for all workers for such determination.

TA–W–32,470; United Sports Apparel, Inc., Pelham, TN: June 5, 1995.

TA–W–32,185; Bugle Boy Industries, North Little Rock, AR: March 4, 1995.

TA–W–32,434; Todd's Sportswear, Inc., Smighville, TN: May 25, 1995.

TA–W–32,393; Todd Uniforms, Maury City, TN: May 7, 1995.

TA–W–32,195; CTS Corp., Bentonville, AR: February 28, 1995.

TA–W–32,287; Crown Vantage (Formerly James River Corp), Parchment, MI: October 23, 1994.

TA–W–32,261; United Technologies Automotive Wiring Systems Div. Plant #80, & #92, Plymouth, Inc: April 9, 1995.

TA–W–32,285; Alcoa Fujikura Ltd—Prototype Plant, Dearborn Heights, MI: April 12, 1995.

TA–W–32,291; Swanknit, Inc., Cohoes, NY: April 26, 1995.

TA–W–32,305; LTNY, Inc., Miami, FL: April 17, 1995.

TA–W–32,322; Footwear By Julius/ Indian Footwear, Bronx, NY: April 29, 1995.

TA–W–32,368; Champion Products, Fitzgerald, GA: May 8, 1995.

TA–W–32,329; Elf Atochem North America, Inc, Buffalo, NY: March 22, 1995.

TA–W–32,417; Maybex Universal Corp., San Diego, CA: May 20, 1995.

TA–W–32,244; Style Sportswear, Inc., Paterson, NJ: April 11, 1995. W–32,293; A.H. Schreiber Co., Inc., Cinnaminson, NJ: April 22, 1995.

TA–W–32,394; Leslie Corp., Anniston, AL: June 3, 1995.

TA–W–32,300; Mallory & Church Corp., Chula Vista, CA: April 24, 1995.

TA–W–32,313; Thermo-o-Disc Co., Inc., Midwest Components Product Group, Newaygo, MI: March 20, 1995

TA–W–32,373; Flexitallic Gasket Co., Pennsauken, NJ: May 10, 1995.

TA–W–32,251; Trout Creek Lumber, Trout Creek, MT: March 26, 1995.

TA–W–32,326; VDO Yazaki Corp., Winchester, VA: April 30, 1995.

TA–W–32,332; Greenfield Research, Inc., Greenfield, OH: May 6, 1995.

TA–W–32,325; ERA Coat, Paterson, NJ: April 26, 1995.

TA–W–32,173; Exxon Co. USA, Midland Div., Midland, TX: October 6, 1996. Including Various Operations in the Following States: A; CA, B; MT, CV; ND, D; NM, E; WY, F; TX: March 26, 1995.

TA–W–32,173G; Exxon Co. USA, New Orleans Div., New Orleans, LA: November 8, 1996. Including Various Operations in the Following States: H; AL, I; FL, J; MS, K: TX: March 26, 1995.

TA–W–32,173L; Exxon Co. USA, Santa Ynez Div., Thousand Oaks, CA: December 15, 1995. Including various Operations in the Following State: M; CA; March 26, 1995.

TA–W–32,173N; Exxon Co., USA, Houston Div., Houston, TX: December 15, 1996. Including Various Operations in the Following States: O; AL, P; AR, O; KS, R; S; TX: March 26, 1995.

Also, pursuant to Title V of the North American Free Trade Agreement Implementation Act (P.L. 103–182) concerning transitional adjustment assistance hereinafter called (NAFTA–TAA) and in accordance with Section 250(a) Subchapter D, Chapter 2, Title II, of the Trade Act as amended, the Department of Labor presents summaries of determinations regarding eligibility to apply for NAFTA–TAA issued during the month of June, 1996.

In order for an affirmative determination to be made and a certification of eligibility to apply for NAFTA–TAA the following group eligibility requirements of Section 250 of the Trade Act must be met:

(1) that a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, (Including workers in any agricultuiral firm or appropriate subdivision thereof) have become totally or partially separated from employment and either—

(2) that sales or production, or both, of such firm or subdivision have decreased absolutely,

(3) that imports from Mexico or Canada of articles like or directly competitive with articles produced by such firm or subdivision have increased, and that the increases in imports contributed importantly to such workers' separations or threat of separation and to the decline in sales or production of such firm or subdivision; or

(4) that there has been a shift in production by such workers' firm or subdivision to Mexico or Canada of articles like or directly competitive with articles which are produced by the firm or subdivision.

Negative Determinations NAFTA–TAA

In each of the following cases the investigation revealed that criteria (3) and (4) were not met. Imports from Canada or Mexico did not contribute importantly to workers' separations. There was no shift in production from the subject firm to Canada or Mexico during the relevant period.

NAFTA–TAA–00941; International Paper, Western Region Land and Timber, Reedsport, OR

NAFTA–TAA–01041; Scrock Cabinet Co., Quaker Main Div., Leesport, PA

NAFTA–TAA–01066; Oneita Industries, Inc., Fingerville Textile Plant, Fingerville, SC

In the following cases, the investigation revealed that the criteria for eligibility have not been met for the reasons specified.

NAFTA–TAA–01084; Forsyth Public School District, Forsyth, MT

The investigation revealed that the workers of the subject firm did not produce an article within the meaning of Section 250(a) of the Trade Act, as amended.

Affirmative Determinations NAFTA–TAA

The following certifications have been issued; the date following the company name & location for each determination references the impact date for all workers for such determination.

NAFTA–TAA–00987; American Olean Title Co., Jackson, TN: April 22, 1995.

NAFTA–TAA–00994; North American Communications, Inc., Dancansville, PA: April 23, 1995.

NAFTA–TAA–01042: SMK Manufacturing, Inc., Placentia, CA: May 16, 1995.

NAFTA–TAA–00998: A.H. Schreiber Co., Inc., Cinnaminson, NJ: April 17, 1995.

NAFTA–TAA–01022; Alcatel Wire & Cable, Inc., Chester, NY: May 7, 1995.

NAFTA–TAA–01074: Alden Electronics, Inc., Westboro, MA: June 7, 1995.

NAFTA–TAA–01079; Yakima Products, Inc., Arcata, CA: May 17, 1995.

NAFTA–TAA–01073; Therm-O-Disc, Inc., Subsidiary of Emerson Electric, Midwest Components products Group, Newaygo, MI: March 2, 1995.

NAFTA–TAA–1050; Motor Coach Industries, International, North American Coach, Inc., Roswell, NM: May 14, 1995.

NAFTA–TAA–1034; IDE Corp., Ideassociates, Bedford, MA: May 14, 1995.

NAFTA–TAA–1098; Daniels McCray Lumber Co., Custom Wood Products Div., St. Joseph, MO: June 6, 1995.

NAFTA–TAA–1097; ROL Manufacturng of America, Inc., Brownsville, TX: June 10, 1995.

NAFTA–TAA–01096; Clevemont Mills, Kings Mountain, NC: May 23, 1995.

NAFTA–TAA–01090; Eaton Corp., Golf Grip Div., Laurinburg, NC: June 13, 1995.

NAFTA–TAA–01013; Greenfield Research, Inc., Greenfield, OH: May 7, 1995.

NAFTA–TAA–01037; Eagle-Picher Industries, Inc., Plastics Div., Huntington, IN: May 14, 1995.

NAFTA–TAA–01051; Robertshaw Controls Co., Columbus Plant, Appliance Controls Div., Grove City, OH: May 28, 1995.

NAFTA–TAA–01046; Pioneer Balloon Co., Willard Operations, Willard, OH: June 3, 1995.

NAFTA–TAA–01056; Triangle Auto Spring Co., Columbia, TN: May 22, 1995.

NAFTA–TAA–01067; Wallace & Tiernan, Inc., Belleville, NJ: June 4, 1995.

NAFTA–TAA–00993; Manhattan Shirt Co., a Div. of Salant Corp., Americus, GA: April 16, 1995.

I hereby certify that the aforementioned determinations were issued during the month of June 1996. Copies of these determinations are available for inspection in Room C–4318, U.S. Department of Labor, 200 Constitution Avenue N.W., Washington, D.C. 20210 during normal business hours or will be mailed to persons who write to the above address.

Dated: July 1, 1996.

Curtis K. Kooser,

Acting Program Manager, Policy & Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 96–17386 Filed 7–8–96; 8:45 am]

BILLING CODE 4510–30–M

[TA–W–31,500, TA–W–31, 500C]

Andover Togs, Incorporated, South Boston, VA, and Stevenson Manufacturing, Stevenson, AL; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 USC 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on October 18, 1995, applicable to all workers of Andover Togs, Incorporated located in South Boston, Virginia. The notice was published in the Federal Register on November 9, 1995 (60 FR 56619). The certification was subsequently amended to include workers at Andover Togs, Incorporated facilities in Pisgah, Alabama and New York, New York. Those amendments were issued March 7 and May 1, 1996, and published in the Federal Register on March 25, 1996 (61 FR 12103) and May 16, 1996 (61 FR 24816), respectively.

At the request of petitioners, the Department reviewed the certification for workers of the subject firm. New information provided by the company shows that worker separations have occurred at the subject firms' Stevenson Manufacturing production facility in Stevenson, Alabama. The workers are engaged in the production of children's apparel.

The intent of the Department's certification is to include all workers of the subject firm who were adversely affected by increased imports of apparel. Accordingly, the Department is again amending the certification to cover the workers of Andover Togs, Incorporated, Stevenson Manufacturing, Stevenson, Alabama.

The amended notice applicable to TA–W–31,500 is hereby issued as follows:

All workers of Andover Togs, Incorporated, South Boston, Virginia (TA–W–31,500), and Stevenson Manufacturing, Stevenson, Alabama (TA–W–31, 500C) engaged in employment related to the production of children's apparel who became totally or partially separated from employment on or after September 15, 1994 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington, D.C., this 26th day of June 1996.

Russell T. Kile,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 96–17376 Filed 7–8–96; 8:45 am]

BILLING CODE 4510–30–M

Investigations Regarding Certifications of Eligibility to Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221 (a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Program Manager of the Office of Trade Adjustment Assistance,

Employment and Training Administration, has instituted investigations pursuant to Section 221 (a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Program Manager, Office of Trade Adjustment Assistance, at the address shown below, not later than July 19, 1996.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Program Manager, Office of Trade Adjustment Assistance, at the address shown below, not later than July 19, 1996.

The petitions filed in this case are available for inspection at the Office of the Program Manager, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

Signed at Washington, D.C. this 17th day of June, 1996.

Russell T. Kile,

Acting Program Manager, Policy & Reemployment Services, Office of Trade Adjustment Assistance.

APPENDIX

[Petitions Instituted On 06/17/96]

TA–W	Subject firm (petitioners)	Location	Date of petition	Product(s)
32,447	BSW International (Wkrs)	Tulsa, OK	04/18/96	Architectural and Engineering.
32,448	General Electric (UE)	Erie, PA	05/07/96	Electric Motors.
32,449	Glencraft Lingerie, Inc. (Wkrs)	New York, NY	05/28/96	Lingerie.
32,450	Texaco Trading & Trans. (Wkrs)	Glendive, MT	05/28/96	Crude Oil Pipeline Transportation.
32,451	Clevemont Mills (Wkrs)	Kings Mountain, NC	05/23/96	Sweat Shirts and Sweat Pants.
32,452	Spartan Mills (Co.)	Spartanburg, SC	03/19/96	Yarn.
32,453	E.I. Du Pont (Co.)	Parlin, NJ	06/03/96	Graphic Arts Film.
32,454	Basic Engineers, Inc. (Wkrs)	Johnstown, PA	06/03/96	Pipe Supports and Hangers.
32,455	ARCO International Oil (Wkrs)	Plano, TX	05/23/96	Administration of Overseas Oil and Gas.
32,456	Lexington Fabrics, Inc. (Wkrs)	Corinth, MS	06/06/96	T-Shirts.
32,457	Sara Lee Knit Products (Co.)	Lumberton, NC	06/04/96	Men's & Boys' Cotton T-Shirts.
32,458	Sara Lee Knit Products (Co.)	Jefferson, NC	06/04/96	Men's and Boy's Cotton T-Shirts.
32,459	Warner's (Wkrs)	Dothan, AL	06/04/96	Ladies' Intimate Apparel.
32,460	UGG Holding Corp. (Wkrs)	Portland, OR	05/20/96	Sheepskin Slippers.
32,461	Oxford of Burgaw (Co.)	Burgaw, NC	06/05/96	Ladies Dresses and Sportswear.
32,462	Prescott Garment Mfg (Wkrs)	Prescott, AR	06/03/96	Men's and Boys' Pajamas.
32,463	Pine River Lumber Co. (Wkrs)	Kenton, MI	05/09/96	Nardwood Lumber.
32,464	Airshield Corp. (Wkrs)	Brownsville, TX	06/04/96	Fiberglass Truck Parts.
32,465	Keystone Thermometrics (Wkrs)	St. Marys, PA	06/05/96	Thermistors, Diodes for Autos.
32,466	Dyna-Safe of Wyoming (Wkrs)	Mountain View, WY	05/31/96	Safety Supervision—Petroleum Industry.
32,467	Rissler and McMurry Co. (Wkrs)	Casper, WY	06/03/96	Truck Bodies.
32,468	Dover Elevator Systems (Wkrs)	Walnut, MS	06/06/96	Programable Controls for Elevators.
32,469	Wallace & Tiernan, Inc. (Co.)	Belleville, NJ	05/29/96	Water and Waste Water Equipment.
32,470	United Sports Apparel (Co.)	Pelham, TN	06/05/96	Athletic Sportswear.
32,471	Lee Thomas, Inc. (CO.)	Los Angeles, CA	05/29/96	Apparel.
32,472	Eaton Corporation (Wkrs)	Glasgow, KY	06/06/96	Axle Components (Ring Gears and Pinions).
32,473	The G & O Manufacturing (UAW)	New Haven, CT	06/03/96	Radiators—Truck, Heavy Equipment.
32,474	Varsity Manufacturing Co (Co.)	Susquehanna, PA	06/05/96	Ladies' Sleepwear.
32,475	Miss Elaine, Inc. (UNITE)	Centralia, IL	06/06/96	Lingerie, Gowns and Sleepwear.

[FR Doc. 96–17378 Filed 7–8–96; 8:45 am]

BILLING CODE 4510–30–M

[TA-W–31,718]

Controlled Power Corporation, Canton, OH; Notice of Revised Determination On Reconsideration

On May 29, 1996, the Department issued an Affirmative Determination Regarding Application for Reconsideration for the workers and former workers of the subject firm. The notice was published in the Federal Register on June 19, 1996 (FR 61 31165).

Investigation findings show that the workers produced low, medium and high voltage metal clad switchgears. The workers were denied TAA because the ''contributed importantly'' test of the Group Eligibility Requirements of the Trade Act was not met. This test is generally determined through a survey of the workers' firm's major declining customers.

Findings on reconsideration show that the major domestic firms which were awarded the contract used foreign suppliers located in Italy, Switzerland, Germany and England for production.

Conclusion

After careful consideration of the new facts obtained on reconsideration, it is concluded that the workers of Controlled Power Corporation of Canton, Ohio were adversely affected by increased imports of articles like or directly competitive with low, medium and high voltage metal clad switchgears produced at the subject firm.

All workers of Controlled Power Corporation, Canton, Ohio who became totally or partially separated from employment on or after November 26, 1994 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of June 1996.

Russell R. Kile,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 96–17379 Filed 7–8–96; 8:45 am]

BILLING CODE 4510–30–M

[TA–W–32,301, TA–W–32,301A]

Hart Schaffner and Marx, Hartmarx Corporation, Chaffee, MO; and Cape Girardeau, MO; Amended Certification Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 USC 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on June 12, 1996, applicable to all workers of Hart Schaffner and Marx/Hartmarx Corporation in Chaffee, Missouri. The certification notice will soon be published in the Federal Register.

At the request of the company, the Department reviewed the certification for workers of the subject firm. New information provided by the company shows that worker separations have occurred at the subject firms' Hart Schaffner and Marx/Hartmarx Corporation in Cape Girardeau, Missouri. The workers are engaged in the administrative, clerical and management services for Schaffner and Marx manufacturing facilities which are under existing certification.

The intent of the Department's certification is to include all workers of the subject firm who were adversely affected by increased imports of men's dress slacks and dress pants. Accordingly, the Department is amending the certification to cover the workers of Hart Schaffner and Marx/ Hartmarx Corporation in Cape Girardeau, Missouri.

The amended notice applicable to TA–W–32,301 is hereby issued as follows:

All workers of Hart Schaffner and Marx/ Hartmarx Corporation in Chaffee, Missouri (TA–W–32,301) and Hart Schaffner and Marx/Hartmarx Corporation in Cape Giraradeau, Missouri (TA–W–32,301A) who became totally or partially separated from employment on or after April 24, 1995 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of June 1996.

Russell T. Kile,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 96–17380 Filed 7–8–96; 8:45 am]

BILLING CODE 4510–30–M

[TA–W–31,798]

Miller Brewing Company, Milwaukee Brewery, Milwaukee, WI; Notice of Revised Determination on Reconsideration

On April 29, 1996, the Department issued an Affirmative Determination Regarding Application for Reconsideration for workers and former workers of the subject firm. The notice was published in the Federal Register on May 16, 1996 (61 FR 24816).

The findings show that the Milwaukee, Wisconsin, plant experienced a decline in employment in January of 1996.

New findings on reconsideration show that United States imports of beer increased both absolutely and as a percentage of U.S. production in 1995 compared with 1994 and also increased absolutely and relatively in April through March, 1995–1996, compared with the same period one year earlier, and that these imports contributed importantly to separations at the subject firms.

Conclusion

After careful consideration of the new facts obtained on reconsideration, it is concluded that the workers at Miller Brewing Company, Milwaukee Brewery, Milwaukee, Wisconsin, were adversely affected by increased imports of articles like or directly competitive with beer produced at the subject firm. In accordance with the provisions of the Act, I make the following revised determination:

All workers of Miller Brewing Company, Milwaukee Brewery, Milwaukee, Wisconsin, who became totally or partially separated from employment on or after December 18, 1994, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed in Washington, D.C., this 26th day of June, 1996.

Russell T. Kile,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 96–17381 Filed 7–8–96; 8:45 am]

BILLING CODE 4510–30–M

[NAFTA–00739, 00739A]

Miller Brewing Company, Milwaukee Brewery, and Pabst Brewing Company, Milwaukee, WI; Notice of Revised Determination on Reconsideration

On April 29, 1996, the Department issued an Affirmative Determination Regarding Application for Reconsideration for workers and former workers of the subject firm. The notice was published in the Federal Register on May 16, 1996 (61 FR 24816).

The findings show that the Milwaukee, Wisconsin, plants experienced declines in employment in January of 1996.

New findings on reconsideration show that United States imports of beer increased both absolutely and as a percentage of U.S. production in 1995 compared with 1994 and also increased absolutely and relatively in April through March, 1995–1996, compared with the same period one year earlier. United States imports from Canada and Mexico were lower but show the same patterns.

Conclusion

After careful consideration of the new facts obtained on reconsideration, it is concluded that the workers at Miller Brewing Company, Milwaukee Brewery, and Pabst Brewing Company, both of Milwaukee, Wisconsin, were adversely affected by increased imports from Mexico and Canada of articles like or directly competitive with beer produced at the subject firms. In accordance with the provisions of the Act, I make the following revised determination.

All workers of Miller Brewing Company, Milwaukee Brewery (NAFTA–00739), and Pabst Brewing Company (NAFTA–00739A), both of Milwaukee, Wisconsin, who became totally or partially separated from employment on or after December 18, 1994, are eligible to apply for NAFTA–TAA under Section 250 of the Trade Act of 1974.

Signed in Washington, D.C., this 26th day of June 1996.

Russell T. Kile,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 96–17387 Filed 7–8–96; 8:45 am]

BILLING CODE 4510–30–M

[TA–W–32,098]

Oshkosh B'Gosh, Columbia Cutting, Columbia, KY; Notice of Revised Determination on Reopening

On April 22, 1996, the Department issued a Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance,

applicable to all workers of Oshkosh B'Gosh, located in Albemarle, North Carolina. The notice was published in the Federal Register on May 16, 1996 (FR 61 24814).

Based on a petitioner inquiry, the Department, on its own motion, reviewed the findings of the investigation. New findings show that the fabric cutting operations performed by workers of the subject firm supported production of apparel at other Oshkosh B'Gosh plants. TAA certifications have been issued for workers of Oshkosh B'Gosh production facilities in various States.

Conclusion

After careful review of the additional facts obtained on reopening, I conclude that increased imports of articles like or directly competitive with apparel contributed importantly to the declines in sales or production and to the total or partial separation of workers of Oshkosh B'Gosh, Columbia Cutting, Columbia, Kentucky. In accordance with the provisions of the Act, I make the following certification:

All workers of Oshkosh B'Gosh, Columbia Cutting, Columbia, Kentucky, who became totally or partially separated from employment on or after March 11, 1995, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington, D.C., this 21st day of June 1996.

Russell T. Kile,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 96–17382 Filed 7–8–96; 8:45 am]

BILLING CODE 4510–30–M

[TA–W–31,799]

Pabst Brewing Company, Milwaukee, WI; Notice of Revised Determination on Reconsideration

On April 29, 1996, the Department issued an Affirmative Determination Regarding Application for Reconsideration for workers and former workers of the subject firm. The notice was published in the Federal Register on May 16, 1996 (61 FR 24816).

The findings show that the Milwaukee, Wisconsin, plant experienced a decline in employment in January of 1996.

New findings on reconsideration show that United States imports of beer increased both absolutely and as a percentage of U.S. production in 1995 compared with 1994 and also increased absolutely and relatively in April through March, 1995–1996, compared with the same period one year earlier, and that these imports contributed importantly to separations at the subject firms.

Conclusion

After careful consideration of the new facts obtained on reconsideration, it is concluded that the workers at Pabst Brewing Company, Milwaukee, Wisconsin, were adversely affected by increased imports of articles like or directly competitive with beer produced at the subject firm. In accordance with the provisions of the Act, I make the following revised determination.

All workers of Pabst Brewing Company, Milwaukee, Wisconsin, who became totally or partially separated from employment on or after December 18, 1944, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed in Washington, D.C., this 26th day of June 1996.

Russell T. Kile,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 96–17383 Filed 7–8–96; 8:45 am]

BILLING CODE 4510–30–M

[TA–W–32,273]

Stevenson Manufacturing, Stevenson, AL: Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on April 29, 1996 in response to a worker petition which was filed April 16, 1996 on behalf of workers at Stevenson Manufacturing, Stevenson, Alabama (TA–W–32,273).

The petitioning group of workers are covered under an existing Trade Adjustment Assistance certification (TA-W-31, 500C). Consequently, further investigation in this case would service no purpose, and the investigation has been terminated.

Signed at Washington, D.C., this 27th day of June 1996.

Linda G. Poole,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 96–17384 Filed 7–8–96; 8:45 am]

BILLING CODE 4510–30–M

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Program Manager of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Program Manager, Office of Trade Adjustment Assistance, at the address shown below, not later than July 19, 1996.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Program Manager, Office of Trade Adjustment Assistance, at the address shown below, not later than July 19, 1996.

The petitions filed in this case are available for inspection at the Office of the Program Manager, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC, this 24th day of June, 1996.

Russell T. Kile,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

APPENDIX

[Petitions Instituted on 06/24/96]

TA–W	Subject firm (petitioners)	Location	Date of petition	Product(s)
32,476	Vanguard Products Corp. (Wkrs)	Berkeley Spring, WV ...	06/11/96	Golf Bags.
32,477	The Dial Corp. (Wkrs)	Omaha, NE	06/10/96	Bar Soap.
32,478	Canal Wire (Wkrs)	Canal Winchester OH	06/12/96	Compact Dishwasher Racks.
32,479	Taylored Clothing Co. (UNITE)	Taylor, PA	06/12/96	Suits and Sport Jackets.
32,480	Beaufab Mills, Inc., (Wkrs)	Stroudsburg, PA	06/10/96	Knit Fabric.
32,481	Chase Ergonomic (Co.)	Albuquerque, NM	06/07/96	Back Support Belts.
32,482	Team 95 (Co.)	Jamestown, TN	06/10/96	Men's Cargo Pants & Shorts.
32,483	Wundies (Co.)	Wellsboro, PA	06/10/96	Ladies' and Girls' Lingerie.
32,484	Wyeth-Ayerst Labs (UFCW)	Mason, MI	06/10/96	Infants Formula.
32,485	Paramount Headwear, Inc (Wkrs)	Advance, MO	6/10/96	Baseball Caps.

[FR Doc. 96–17385 Filed 7–8–96; 8:45 am]

BILLING CODE 4510–30–M

Trade Adjustment Assistance/NAFTA Financial Status Report/Request for Funds; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Employment and Training Administration is soliciting comments concerning the proposed extension of the Trade Adjustment Assistance/North American Free Trade Agreement (NAFTA) Transitional Adjustment Assistance program Financial Status Report/Request for Funds. A copy of the proposed information collection request (ICR) can be obtained by contacting the office listed below in the addressee section of this notice.

DATES: Written comments must be submitted to the office listed in the **ADDRESSEE** section below on or.

The Department of Labor is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

ADDRESSES: Jess Aragon or Joseph Nelson, 200 Constitution Avenue, N.W. Washington D.C. 20210, 202–219–7979 (this is not a toll free number). FAX number 202–219–6564.

SUPPLEMENTARY INFORMATION:

I. Background

The amendments to the Trade Act contained in the Omnibus Trade and Competitiveness Act (OTCA) of 1988 (P.L. 100–418) and Title 5 of the North American Free Trade Agreement Implementation Act (P.L. 103–182) of 1993 made some significant changes which affect the way the Trade Adjustment Assistance and North American Free Trade Agreement (NAFTA) Adjustment Assistance programs are funded and administered. These changes made enrollment in training programs an entitlement for workers adversely affected by imports (Trade program) or by imports from Canada or Mexico (NAFTA program). Thus, the Trade program and NAFTA trade program consists of entitlements for trade readjustment allowances, job search allowances, job relocation allowances and training. In order for workers to continue to receive entitlement to trade adjustment allowances, they must be enrolled in a training program approved by the Secretary of Labor (1423 of OTCA) for the trade program and (section 250 of the NAFTA Implementation Act) for the NAFTA program.

Although training becomes an entitlement under both programs, the OTCA imposed a training cap in section 236 for the Trade program and under subchapter D for the NAFTA program. The statutory cap is $80 million for the Trade program and $30 million for the NAFTA program. The purpose of the collection of this information on the Form ETA–9023 is to be able to monitor expenditures for both programs to ensure that the statutory ceilings are not exceeded.

Additionally, the Secretary of Labor is responsible for ensuring that resources are equitably distributed to the States. This form allows the ETA the ability to evaluate a State's need for resources and to redistribute resources among States as necessary.

II. Current Actions

The ETA–9023 has been successfully utilized by the ETA and the States with only minor modifications since FY 1989. The Federal Register Notice requests an extension of the ETA–9023 for both the TAA and NAFTA programs. Overall, States have done a commendable job in completing the form with relatively minor problems or questions raised by the States on the form. The ETA–9023 has been extremely important to the ETA over the last several years because the entire $80 million available, under the statutory cap for the Trade program for training was allocated to the States. The ETA–9023 report was critical in allowing ETA to be able to redistribute resources equitably among States so training activity would not be discontinued in some States.

Type of Review: Revision.

Title: Trade Adjustment Assistance/ NAFTA Financial Status Report/Request for Funds.

OMB Number: 1205–0275.

Agency Number: ETA–9023.

Affected Public: State Government, State Employment Security Agencies.

Cite/Reference/Form/etc: See below.

Cite/reference	Total respondents	Frequency	Total responses	Average time per responses (hours)	Burden
TAA Rptg	50	5	250	2	500
NAFTA Rptg	50	5	250	2	500
Totals	.....	.....	500	.....	1,000

The total cost is $26.00×100 hours=$26,000.

Comments submitted in response to this comment request will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: July 2, 1996.

Jack H. Rapport,

Deputy Comptroller, Employment and Training Administration.

[FR Doc. 96–17375 Filed 7–8–96; 8:45 am]

BILLING CODE 4510–30–M

[NAFTA–001033]

Western Energy Company, Colstrip, MT; Notice of Termination of Investigation

Pursuant to Title V of the North American Free Trade Agreement Implementation Act (P.L. 103–182) concerning transitional adjustment assistance, hereinafter called (NAFTA–TAA), and in accordance with Section 250(a), Subchapter D, Chapter 2, Title II, of the Trade Act of 1974, as amended (19 USC 2273), an investigation was initiated on May 16, 1996 in response to a petition filed on behalf of workers at Western Energy Company in Colstrip, Montana.

The petitioning worker group is already covered under an amended active certification (NAFTA–00946A). Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, D.C., this 27th day of June 1996.

Linda G. Poole,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 96–17388 Filed 7–8–96; 8:45 am]

BILLING CODE 4510–30–M

[TA–W–31,962]

Blue Chip Products, Incorporated, Morrisville, PA; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on March 4, 1996 in response to a worker petition which was filed on March 4, 1996 on behalf of workers at Blue Chip Products, Incorporated, Morrisville, Pennsylvania.

The petitioning group of workers is subject to a previous investigation for which a negative determination has been issued (NAFTA–00837). In the North American Free Trade Agreement-Trade Adjustment Assistance investigation it was determined that based on the facts in the case, there was no evidence of adverse import impact from countries other than Canada or Mexico. At that time, the case was reviewed and it was determined that a certification with respect to that petition couldn't be issued in accordance with the requirements of Section 222 of the Trade Act. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed in Washington, D.C., this 26th day of June 1996.

Russell T. Kile,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 96–17377 Filed 7–8–96; 8:45 am]

BILLING CODE 4510–30–M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 96–066]

Government-Owned Inventions, Available for Licensing

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of Availability of Inventions for Licensing.

SUMMARY: The inventions listed below are assigned to the National Aeronautics and Space Administration, have been filed in the United States Patent and Trademark Office, and are available for licensing.

Copies of patent applications cited are available from the Office of Patent Counsel, Jet Propulsion Laboratory, Mail Code SPJ, Pasadena, CA 91109. Claims are deleted from the patent applications to avoid premature disclosure.

DATES: July 9, 1996.

FOR FURTHER INFORMATION CONTACT: Thomas H. Jones, Patent Counsel, Mail Code SPJ, NASA Management Office-JPL, Pasadena, CA 91109; telephone (818) 354–5179, fax (818) 354–6051.

NASA Case No. NPO–19,143–2: Long-Wavelength PtSI Infrared Detectors and Method of Fabrication Thereof;

NASA Case No. NPO–18,414–3: Synchronous Parallel System for Emulation and Discrete Event Simulation;

NASA Case No. NPO–18,518–1: Solid-State Image Sensor with Focal-Plane Digital Photon-Counting Pixel-Array;

NASA Case No. NPO–18,983–2: Scalable Wrap-Around Shuffle Exchange Network with Deflection Routing;

NASA Case No. NPO–18,836–2: Method of Producing Buried Porous Silicon-Germanium Layers in Monocrystalline Silicon Lattices;

NASA Case No. NPO–19,098–1: Resonant Attachment Method for Low Level Trace Oxygen Contaminant Detection;

NASA Case No. NPO–19,428–1: Varying Potential Silicon Carbide Gas Sensor;

NASA Case No. NPO–19,423–1: Parallel Promimity Detection for Computer Simulation;

NASA Case No. NPO–19,002–1: Analysis of Supercritical-Extracted Chelated Metal Ions from Mixed Organic-Inorganic Samples;

NASA Case No. NPO–18,756–1: Point Relay Scanner Utilizing Ellipsoidal Mirrors;

NASA Case No. NPO–19,108–2: Digital Camera with Apparatus for Authentication of Images Produced from an Image File;

NASA Case No. NPO–19,414–1: Temperature Compensated Sapphire Resonator for Ultrastable Oscillator Operating at Temperatures Near 77 degrees Kelvin;

NASA Case No. NPO–19,418–1: Modulated Source Interferometry;

NASA Case No. NPO–19,442–1: Composite Material Switches;

NASA Case No. NPO–19,430–1: Polarization Independent Electro-Optic Modulator;

Dated: June 25, 1996.

Edward A. Frankle,

General Counsel.

[FR Doc. 96–17306 Filed 7–8–96; 8:45 am]

BILLING CODE 7510–01–M

[Notice 96–067]

Government-Owned Inventions, Available for Licensing

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of Availability of Inventions for Licensing.

SUMMARY: The inventions listed below are assigned to the National Aeronautics and Space Administration, have been filed in the United States Patent and Trademark Office, and are available for licensing.

Copies of patent applications cited are available from the Office of Patent Counsel, Johnson Space Center, Mail Code HA, Houston, TX 77058. Claims are deleted from the patent applications to avoid premature disclosure.

DATES: July 9, 1996.

FOR FURTHER INFORMATION CONTACT: Ed Fein, Patent Counsel, Lyndon B. Johnson Space Center, Mail Code HA, Houston, TX 77058; telephone (713) 483–0837, fax (713) 244–8452.

NASA Case No. MSC–22,540–1: High Performance Zinc Anode for Battery;

NASA Case No. MSC–22,746–1: Method and Apparatus for Modulating Light Using;

NASA Case No. MSC–22,483–1: Microwave Treatment for Cardiac Arthythmias;

NASA Case No. MSC–22,360–2: Absorbent Pads for Containment, Neutralization, and Clean-Up of Environmental Spills Containing;

NASA Case No. MSC–22,745–1: Method and Apparatus for Coupling Space Vehicles;

NASA Case No. MSC–22,424–3: Rotary Blood Pump;

Dated: June 25, 1996.

Edward A. Frankle,

General Counsel.

[FR Doc. 96–17307 Filed 7–8–96; 8:45 am]

BILLING CODE 7510–01–M

[Notice 96–068]

Government-Owned Inventions, Available for Licensing

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of Availability of Inventions for Licensing.

SUMMARY: The inventions listed below are assigned to the National Aeronautics and Space Administration, have been filed in the United States Patent and Trademark Office, and are available for licensing.

Copies of patent applications cited are available from the Office of Patent Counsel, Kennedy Space Center, Mail Code DE–TPO, Kennedy Space Center, FL 32899. Claims are deleted from the patent applications to avoid premature disclosure.

DATES: July 9, 1996.

FOR FURTHER INFORMATION CONTACT: William J. Sheehan, Patent Counsel, Mail Code DE–TPO, Kennedy Space Center, FL 32899; telephone (407) 867–2544, fax (407) 867–2050.

NASA Case No. KSC–11,694: Balanced Rotating Spray Tank and Pipe Cleaning and Cleanliness Verification System;

NASA Case No. KSC–11,685: Portable Light Source Unit for Simulating Fires;

NASA Case No. KSC–11,722: Optical Detector Calibrator System;

NASA Case No. KSC–11,775: Flame Detector;

Dated: June 27, 1996.

Edward A. Frankle,

General Counsel.

[FR Doc. 96–17308 Filed 7–8–96; 8:45 am]

BILLING CODE 7510–01–M

[Notice 96–072]

Government-Owned Inventions, Available for Licensing

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of Availability of Inventions for Licensing.

SUMMARY: The inventions listed below are assigned to the National Aeronautics and Space Administration, have been filed in the United States Patent and Trademark Office, and are available for licensing.

Copies of patent applications cited are available from the Office of Patent Counsel, Lewis Research Center, Mail Code LE–LAW, Cleveland, OH 44135. Claims are deleted from the patent applications to avoid premature disclosure.

DATE: July 9, 1996.

FOR FURTHER INFORMATION CONTACT: Kent N. Stone, Patent Counsel, Mail Code LE–LAW, Lewis Research Center, Cleveland, OH 44135; telephone (216) 433–2320, fax (216) 433–6790.

NASA Case No. LEW–15; 956–2: Method and Apparatus for the Detection of Hydrogen Using a PdTi Metal Alloy;

NASA Case No. LEW–15, 665–2: Method and Apparatus for Pressure Pulse Arcjet Starting;

NASA Case No. LEW–16, 228–1: Precision Thickness Variation Mapping Via One-Transducer Ultrasonic High Resolution Profilometry for Sample with Irregular or Rough Surfaces.

Dated: July 1, 1996.

Edward A. Frankle,

General Counsel.

[FR Doc. 96–17441 Filed 7–8–96; 8:45 am]

BILLING CODE 7510–01–M

[Notice 96–069]

Notice of Prospective Patent License

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of Prospective Patent License.

SUMMARY: NASA hereby gives notice that HITCO Technologies, Inc., of Gardena, California 90249, Materials and Electrochemical Research Corporation (MER), of Tucson, Arizona 85706, P&P Machine Tool, Inc., of Fort Wayne, Indiana 46803, have each applied for partially exclusive licenses to practice the following patented inventions: U.S. Patent No. 4,683,809, ''LIGHTWEIGHT PISTON''; U.S. Patent No. 4,736,676, ''COMPOSITE PISTON''; U.S. Patent No. 4,909,133, ''LIGHTWEIGHT PISTON ARCHITECTURE''; and for the following inventions: NASA Case LAR–15,094–1, entitled ''CONCEPT FOR A RINGLESS CARBON-CARBON PISTON IN INTERNAL COMBUSTION ENGINES''; NASA Case No. LAR–15,462–1, entitled ''INTEGRAL RING CARBON-CARBON PISTON''; NASA Case No. LAR–15,492–1, entitled ''CARBON-CARBON PISTON ARCHITECTURES''; and NASA Case No. LAR–15,493–1, entitled ''PISTON AND CYLINDERS MADE OF CARBON-CARBON COMPOSITE.'' Written objections to the prospective grant of a license should be sent to George F. Helfrich, Patent Counsel, Langley Research Center.

DATES: Responses to this notice must be received by Sept. 9, 1996.

FOR FURTHER INFORMATION CONTACT: George F. Helfrich, Patent Counsel, Langley Research Center, Mail Code

212, Hampton, VA 23681; telephone (804) 864–9260.

Dated: June 27, 1996.

Edward A. Frankle,

General Counsel.

[FR Doc. 96–17309 Filed 7–8–96; 8:45 am]

BILLING CODE 7510–01–M

NATIONAL COMMUNICATIONS SYSTEM

Telecommunications Service Priority System Oversight Committee

AGENCY: National Communications System (NCS).

ACTION: Notice of meeting.

A meeting of the Telecommunications Service Priority (TSP) System Oversight Committee will convene Tuesday, August 13, 1996 from 9 a.m. to 4:30 p.m. The meeting will be held at the SeaTac Marriott, 3201 S. 176th Street, Seattle, WA.

—Opening/Administrative Remarks
—Review Action Items from March meeting
—TSP Program Office Activities
—Cellular Priority Access Service Update
—TSP & DISN
—Vendor Reconciliation Status
—User Revalidation & User Reconciliation
—Migration to Client Server Platform Status
—Old Business/New Business

Anyone interested in attending or presenting additional information to the Committee, please contact LCDR Angela Abrahamson, Manager, TSP Program Office, (703) 607–4930, or Betty Hoskin (703) 607–4932 by August 1, 1996.

Dennis Bodson,

Federal Register Liaison Officer, National Communications System.

[FR Doc. 96–17342 Filed 7–8–96; 8:45 am]

BILLING CODE 3610–05–M

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meeting

AGENCY HOLDING MEETING: National Science Foundation, National Science Board.

DATE AND TIME: July 17, 1996—1:00 p.m.—Closed Session; July 18, 1996—2:00 p.m.—Closed Session; July 19, 1996—9:30 a.m.—Open Session.

PLACE: National Science Foundation, 4201 Wilson Boulevard, Room 1235, Arlington, Virginia 22230.

STATUS: Part of this meeting will be open to the public. Part of this meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

Wednesday, July 17, 1996

Closed session (1:00 p.m.–2:00 p.m.)
—NSF Budget

Thursday, July 18, 1996

Closed session (2:00 p.m.–5:30 p.m.)
—Minutes, May 1996 Meeting
—Awards and Agreements
—NSF Budget

Friday, July 19, 1996

Open session (9:30 a.m.–10:30 a.m.)
—Minutes, May 1996 Meeting
—Closed Session Agenda Items—August 1996 Meeting
—Chairman's Report
—Director's Report
—Reports from Committees
—Other Business
—Adjourn

Marta Cehelsky,

Executive Officer.

[FR Doc. 96–17584 Filed 7–5–96; 1:21 pm]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

Agency Information Collection Activities: Submission for Office of Management and Budget (OMB) Review; Comment Request

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of the OMB review of information collection and solicitation of public comment.

SUMMARY: The NRC has recently submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

1. Type of submission: Revision.
2. The title of the information collection: 10 CFR Part 35, ''Medical Use of Byproduct Material.''
3. The form number: Not applicable.
4. How often the collection is required: Required reports are collected and evaluated on a continuing basis as needed due to a change in programs or as events occur.
5. Who will be required or asked to report: Physicians and medical institutions who are applicants for, or hold, an NRC license authorizing the administration of byproduct material, or its radiation, to humans for medical use.
6. An estimate of the number of responses: 1,882,283 responses from NRC licensees and 4,705,652 responses from Agreement State licensees.
7. The estimated number of annual respondents: 1,982 NRC licensees and 4,955 Agreement State licensees.
8. An estimate of the total number of hours needed annually to complete the requirement or request: 376,407 hours for NRC licensees and 942,820 hours for Agreement State licensees.
9. An indication of whether Section 3507(d), Pub. L. 104–13 applies: Not applicable.
10. Abstract: 10 CFR Part 35, ''Medical Use of Byproduct Material,'' contains requirements that apply to NRC licensees who are authorized to administer byproduct material, or its radiation, to humans for medical use. The information in the required reports and records is used by the NRC to ensure that public health and safety is protected, and that the licensee possession and use of byproduct material is in compliance with license and regulatory requirements. The revision is a net increase adjustment in burden resulting from an increase in the number of affected licensees, a reevaluation of the time required to perform individual activities and the number of times those activities are performed, and an addition of burden associated with three sections, two of which are a result of rulemaking, and one which was inadvertently omitted during the last evaluation of burden.

A copy of the submittal may be viewed free of charge at the NRC Public Document Room, 2120 L Street, NW (Lower Level), Washington, DC. Members of the public who are in the Washington, DC, area can access the submittal via modem on the Public Document Room Bulletin Board (NRC's Advance Copy Document Library) NRC subsystem at FedWorld, 703–321–3339. Members of the public who are located outside of the Washington, DC, area can dial FedWorld, 1–800–303–9672, or use the FedWorld Internet address: fedworld.gov (Telnet). The document will be available on the bulletin board for 30 days after the signature date of this notice. If assistance is needed in accessing the document, please contact the FedWorld help desk at 703–487–4608. Additional assistance in locating the document is available from the NRC Public Document Room, nationally at 1–800–397–4209, or within the Washington, DC, area at 202–634–3273.

Comments and questions should be directed to the OMB reviewer by August 8, 1996: Peter Francis, Office of Information and Regulatory Affairs (3150–0010), NEOB–10202, Office of Management and Budget, Washington, DC 20503.

Comments can also be submitted by telephone at (202) 395–3084.

The NRC Clearance Officer is Brenda Jo. Shelton, (301) 415–7233.

Dated at Rockville, Maryland, this 1st day of July 1996.

For the Nuclear Regulatory Commission.

Gerald F. Cranford,

Designated Senior Official for Information Resources Management.

[FR Doc. 96–17446 Filed 7–8–96; 8:45 am]

BILLING CODE 7590–01–P

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Nuclear Regulatory Commission.

DATE: Weeks of July 8, 15, 22, and 29, 1996.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of July 8

Wednesday, July 10

11:30 a.m.—Affirmation Session (PUBLIC MEETING) (if needed)

Week of July 15—Tentative

There are no meetings scheduled for the Week of July 15.

Week of July 22—Tentative

There are no meetings scheduled for the Week of July 22.

Week of July 29—Tentative

Monday, July 29

10:00 a.m.—Briefing on Uranium Recovery Program (PUBLIC MEETING); (Contact: Joe Holonich, 301–415–6643).

Tuesday, July 30

10:00 a.m.—Briefing by Nuclear Waste Technical Review Board (PUBLIC MEETING).

2:00 p.m.—Briefing on Status of Staff Actions on Industry Restructuring and Deregulation; (PUBLIC MEETING); (Contact: Scott Newberry, 301–415–1183).

Wednesday, July 31

2:00 p.m.—Briefing on EEO Program (PUBLIC MEETING); (Contact: Ed Tucker, 301–415–7382).

Thursday, August 1

10:00 a.m.—Briefing on Spent Fuel Pool Cooling Issues (PUBLIC MEETING); (Contact: George Hubbard, 301–415–2870).

11:30 a.m.—Affirmation Session (PUBLIC MEETING); (if needed).

THE SCHEDULE FOR COMMISSION MEETINGS IS SUBJECT TO CHANGE ON SHORT NOTICE. TO VERIFY THE STATUS OF MEETINGS CALL (RECORDING)—(301) 415–1292. CONTACT PERSON FOR MORE INFORMATION: Bill Hill (301) 415–1661.

The NRC Commission Meeting Schedule can be found on the Internet at:

http://www.nrc.gov/SECY/smj/schedule.htm.

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to it, please contact the Office of the Secretary, Attn: Operations Branch, Washington, D.C. 20555 (301–415–1963).

In addition, distribution of this meeting notice over the internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to alb@nrc.gov or dkw@nrc.gov.

William M. Hill, Jr.,

SECY Tracking Officer, Office of the Secretary.

[FR Doc. 96–17553 Filed 7–5–96; 10:52 am]

BILLING CODE 7590–01–M

OVERSEAS PRIVATE INVESTMENT CORPORATION

Submission for OMB Review; Comment Request

AGENCY: Overseas Private Investment Corporation, IDCA.

ACTION: Request for comments.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to publish a notice in the Federal Register notifying the public that the Agency is preparing an information collection request for OMB review and approval and to request public review and comment on the submission. Comments are being solicited on the need for the information, its practical utility, the accuracy of the Agency's burden estimate, and on ways to minimize the reporting burden, including automated collection techniques and uses of other forms of technology. The proposed form under review is summarized below.

DATES: Comments must be received by no later than September 9, 1996.

ADDRESSES: Copies of the subject form and the request for review prepared for submission to OMB may be obtained from the Agency Submitting Officer. Comments on the form should be submitted to the Agency Submitting Officer.

FOR FURTHER INFORMATION CONTACT: OPIC Agency Submitting Officer: Lena Paulsen, Manager, Information Center, Overseas Private Investment Corporation, 1100 New York Avenue, N.W., Washington, D.C. 20527; 202/336–8565.

Summary of Form Under Review

Type of Reqeuest: Renewal of an existing form.

Title: Foreign Shareholder Disclosure Report—In Support of an Application for Financing.

Form Number: OPIC 139.

Frequency of Use: Once per each non-U.S. sponsor per project.

Type of Respondents: Individuals, Business, or other institutions.

Standard Industrial Classification Codes: All.

Description of Affected Public: Non-U.S. Companies or Individuals investing in any project financing by OPIC.

Reporting Hours: two hours per response

Number of Responses: 70 per year.

Federal Cost: $2,625

Authority for Information Collection: Sections 231 and 234 (b) and (c) of the Foreign Assistance Act of 1961, as amended.

Abstract (Needs and Uses): The Foreign Shareholder Disclosure Report—In Support of an Application for Financing, requests information as required per OPIC's governing legislation. Such information is needed to determine whether a project and its non-U.S. sponsor meet eligibility criteria for OPIC financing, specifically with regard to effects on the U.S. economy.

Dated: July 2, 1996.

James R. Offutt,

Assistant General Counsel, Department of Legal Affairs.

[FR Doc. 96–17366 Filed 7–8–96; 8:45 am]

BILLING CODE 3210–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–37384; File No. SR–Amex-96–22]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the American Stock Exchange, Inc. Relating to Fee Changes

June 28, 1996.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''), 15 U.S.C. § 78s(b)(1), notice is hereby given that on June 25, 1996, 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 self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Amex proposes to waive its equity transaction charges on

proprietary equity trades in paired securities effected on the Exchange floor by options specialists and registered options traders (''ROTs'').

The text of the proposed rule change is available at the Office of the Secretary, 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

In 1991, the Exchange imposed transaction charges on proprietary equity trades by members and member organizations, while maintaining an exemption for proprietary trades of equity specialists in view of the market making function they perform.[1] Subsequently, in 1995, the Exchange waived such charges on proprietary equity trades effected by Registered Equity Market Markers (''REMMs'') in order to facilitate their market making function as set forth in Exchange Rule 114 and place them on an equal footing with Exchange equity specialists.[2]

When option specialists and ROTs[3] that trade ''paired securities'' (*i.e.*, where both the option and underlying equity security are traded on the Amex) hedge an option position by trading in the underlying Amex listed security, they are currently subject to the Exchange's transaction charge on proprietary equity trades. The Exchange is now waiving its equity transaction charge imposed on proprietary equity trades by option specialists and ROTs hedging in paired securities. Option specialists and ROTs, like equity specialists and REMMs, perform a market making function in their assigned securities and the Exchange believes it is equitable that they be treated the same with respect to transaction charges on proprietary equity trades used for hedging purposes.

The Exchange believes the proposed rule change is consistent with Section 6(b) of the Act in general and furthers the objectives of Section 6(b)(4) in particular in that they provide for the equitable allocation of reasonable dues, fees, and other charges among Amex members, issuers, and other persons using the Exchange's facilities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes the proposed rule change will impose no burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The fee change has become effective pursuant to Section 19(b)(3)(A) of the Act and subparagraph (e)(2) of Rule 19b–4. At any time within 60 days of the filing of such fee change, the Commission may summarily abrogate such fee 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, N.W., Washington, D.C. 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 at the Commission's Public Reference Section, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of such filing will also be available for inspection and copying at the principal office of the Amex. All submissions should refer to File No. SR–Amex–96–22 and should be submitted by July 30, 1996.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[4]

Jonathan G. Katz,

Secretary.

[FR Doc. 96–17354 Filed 7–8–96; 8:45 am]

BILLING CODE 8010–01–M

[1] *See* Securities Exchange Act Release No. 28794 (Jan. 17, 1991), 56 FR 2964 (Jan. 25, 1991).

[2] *See* Securities Exchange Act Release No. 36081 (Aug. 10, 1995), 60 FR 42635 (Aug. 16, 1995).

[3] ROTs are members that trade on a proprietary basis on the Floor in one or more designated classes of options. Exchange Rule 958 sets forth the obligations and requirements under which ROTs are permitted to conduct such proprietary trading on the Floor. When trading in their designated options, ROTs are required under the Rule to contribute to the maintenance of a fair and orderly market in such options, engaging in dealings in such options which contribute to price continuity or depth or minimize the effects of a temporary disparity between the supply and demand for such options. Thus, while not subject to an option specialist's continuous market making obligation, when ROTs effect proprietary equity trades on the Floor, they are required to comply with the same market making obligations as option specialists.

[4] 17 CFR 200.30–3(a)(12) (1994).

[Release No. 34–37392; File No. SR–DCC–96–08]

Self Regulatory Organizations; Delta Clearing Corp.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to the Addition of Patriot Securities, Inc. as an Interdealer Broker for Delta Clearing Corp.'s Repurchase Agreement Clearance System

July 1, 1996.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on June 12, 1996, Delta Clearing Corp. (''DCC'') 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 primarily by DCC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The purpose of the proposed rule change is to give notice that DCC has authorized Patriot Securities, Inc. (''Patriot'') to act as an interdealer broker in DCC's over-the-counter clearance and settlement system for repurchase agreement and reverse repurchase agreement (''repos'') transactions involving U.S. Treasury securities.

[1] 15 U.S.C. 78s(b)(1) (1988).

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, DCC 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. DCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.[2]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

Through its repo clearing system, DCC clears repo transactions that have been agreed to by DCC participants through the facilities of interdealer brokers that have been specially authorized by DCC (''authorized brokers'') to offer their services to DCC participants.[3] Currently, Liberty Brokerage, Inc., RMJ Special Brokerage Inc., Euro Brokers Maxcor Inc., Tullet and Tokyo Securities Inc., and Tradition (Government Securities), Inc., are authorized brokers.[4] The purpose of the proposed rule change is to give notice that DCC has authorized Patriot to act as a broker in DCC's clearance and settlement system for repo trades.

The proposed rule change will facilitate the prompt and accurate clearance and settlement of securities transactions, and therefore, the proposed rule change is consistent with the requirements of the Act, specifically Section 17A of the Act, and the rules and regulations thereunder.[5]

(B) Self-Regulatory Organization's Statement on Burden on Competition

DCC does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

Comments were neither solicited nor received.

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)(iii) of the Act[6] and Rule 19b–4(e)(4) thereunder[7] in that the proposal effects a change in an existing service of a registered clearing agency that does not adversely affect the safeguarding of securities or funds in the custody or control of the clearing agency or for which it is responsible and does not significantly affect the respective rights or obligations of the clearing agency or persons using the service. At any time within sixty days of the filing of the proposed 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, N.W., Washington, D.C. 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 communication 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, N.W., Washington, D.C. 20549. Copies of such filing also will be available for inspection and copying at DCC. All submissions should refer to File No. SR–DCC–96–08 and should be submitted by July 30, 1996.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[8]

Jonathan G. Katz,

Secretary.

[FR Doc. 96–17352 Filed 7–8–96; 8:45 am]

BILLING CODE 8010–01–M

[2] The Commission has modified parts of these statements.

[3] For a complete description of the DCC's repo clearance system, see Securities Exchange Act Release No. 36367 (October 13, 1995), 60 FR 54095.

[4] Securities Exchange Act Release Nos. 36367 (October 13, 1994), 60 FR 54059; 36901 (February 28, 1996), 61 FR 8991; 37212 (May 14, 1996), 61 FR 25722; and 37235 (May 20, 1996), 61 FR 26942.

[5] 15 U.S.C. 78q–1 (1988).

[6] 15 U.S.C. 78s(b)(3)(A)(iii) (1988).

[7] 17 CFR 240.19b–4(e)(4) (1995).

[8] 17 CFR 200.30–3(a)(12) (1995).

[Release No. 34–37390; International Series Release No. 999; File No. SR–ISCC–96–03]

Self-Regulatory Organizations; International Securities Clearing Corporation; Notice of Filing of a Proposed Rule Change Relating to the Clearing Fund Formula

July 1, 1996.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on May 16, 1996, the International Securities Clearing Corporation (''ISCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change (File No. SR–ISCC–96–03) as described in Items I, II, and III below, which items have been prepared primarily by ISCC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Changes

ISCC is filing the proposed rule change to extend approval of its clearing fund formula.[2]

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Changes

In its filing with the Commission, ISCC 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. ISCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.[3]

[1] 15 U.S.C. § 78s(b)(1) (1988).

[2] The Commission temporarily approved two previous ISCC proposed rule changes amending ISCC's clearing fund formula. Securities Exchange Act Release No. 35970 (July 13, 1995), 60 FR 37698 [File No. SR–ISCC–95–03] (notice of filing and order granting accelerated approval on a temporary basis of ISCC's clearing fund formula) and Securities Exchange Act Release No. 34392 (July 15, 1994), 59 FR 37798 [File No. SR–ISCC–94–1] (order temporarily approving on an accelerated basis ISCC's clearing fund formula).

[3] The Commission has modified these summaries.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule is to extend approval of ISCC's clearing fund formula.[4] ISCC is obligated to the London Stock Exchange (''LSE'') to pay for all securities delivered to ISCC through the ISCC–LSE link. ISCC has no responsibility to complete open pending trades (*i.e.*, once a member fails, ISCC no longer accepts delivery of securities for such member through the link). To adequately cover ISCC's exposure, each member's clearing fund deposit requirement is calculated and collected on a weekly basis. Each member is required to deposit the greater of (a) the largest deposit requirement imposed over the last 365 day period or (b) the deposit that would be required based on the clearing fund calculation using trades due to settle over the next week. Calculations are made each Tuesday, and members are required to deposit additional clearing fund amounts within three days.[5]

ISCC's clearing fund formula is: (Gross Debit Value) x (Market Risk Factor) + (Foreign Exchange Factor).[6] The Gross Debit Value is a member's largest single daily gross debit value based on debit values for five consecutive business days including the day on which the calculation is performed less 15% of the Institutional Net Settlement (''INS'') receive value for that same day.[7] The Market Risk Factor is based on the largest calculated percentage change in the Financial Times Index over a six day period over a minimum of 365 days.[8] The Market Risk Factor will continue to be set at 7%. The Foreign Exchange Factor is based in part on the Estimated Foreign Exchange Volatility, which is an amount that is equal to the largest one day percentage change in the U.S. dollar/British pound foreign exchange rate over a minimum of 365 days.[9] The Estimated Foreign Exchange Volatility will continue to be set at 4%.[10] The Market Risk Factor and Foreign Exchange Risk Factor for members on surveillance can be increased in the discretion of ISCC by 3%, 5%, and 7% for members on Advisory, Class A, and Class B surveillance, respectively.

The proposed rule change will permit ISCC to safeguard securities and funds in its custody or control and is therefore consistent with Section 17A of the Act[11] and the rules and regulations thereunder.

(B) Self-Regulatory Organization's Statement on Burden on Competition

ISCC does not believe that the proposed rule change will have an impact on 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

ISCC will notify the Commission of any written comments received by ISCC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within thirty-five 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 ninety 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 ISCC 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 20549. Copies of such filing will also be available for inspection and copying at the principal office of ISCC. All submissions should refer to the file number (ISCC–96–03) and should be submitted by: July 30, 1996.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[12]

Jonathan G. Katz,

Secretary.

[FR Doc. 96–17356 Filed 7–8–96; 8:45 am]

BILLING CODE 8010–01–M

[4] In 1986, ISCC and the London Stock Exchange (''LSE'') entered into a linkage agreement which allows ISCC to obtain comparison and settlement services in the United Kingdom from the LSE on behalf of ISCC members. At that time, the LSE settled trades on a fornightly basis with all trades that occurred during a two week period settling on the same day. On July 18, 1994, the LSE moved to a ten day rolling settlement cycle with trades settling ten days after trade date. On June 26, 1995, the LSE moved to a five day rolling settlement period. In response to the change to a rolling settlement cycle, ISCC adjusted its method of calculating its clearing fund requirements.

[5] For example, ISCC calculates a member's clearing fund requirement on Tuesday, August 2, based on trades due to settle on Tuesday, August 2, through Monday, August 8 (*i.e.*, trades conducted on Tuesday, July 26, through Monday, August 1). Because an ISCC member has three business days after the calculation to make additional deposits, under the five day rolling settlement cycle, ISCC generally is calculating and collecting clearing fund contributions based on trades which already have settled. Under the prior ten day rolling settlement system, the clearing fund formula was based on the actual largest daily obligation of a member during the relevant time period, and the clearing fund deposit could be calculated and collected prior to the settlement day.

[6] Members will continue to be required to contribute a minimum of $50,000 to the clearing fund.

[7] Under the INS system, redeliveries of securities from ISCC members to institutional participants can occur automatically through the LSE. Therefore, ISCC generally is not required to pay the LSE for these securities. The debits arising from these redeliveries may be offset only partially because these securities may be reclaimed (*i.e.*, returned) by the receiver, and in such circumstance, ISCC is liable to the LSE for the full value of the reclamation.

[8] ISCC bases its clearing fund calculations on the assumption that it will take one day to sell all of a defaulting participant's positions. Under a five day settlement period, this results in a six day exposure for market risk with five days between trade date and settlement date and one day between settlement date and close out of positions. There also is a one day exposure for foreign exchange risk because ISCC converts U.S. dollars to British pounds on the settlement date and converts the proceeds from the sale of the positions to U.S. dollars the following day.

[9] The Foreign Exchange Factor is the product of the Gross Debit Value and the Estimated Foreign Exchange Volatility less the produce of the Gross Debit Value times the Market Risk Factor times the Estimated Foreign Exchange Volatility.

[10] During the period from 1989 to 1992, the maximum fluctuation in the U.S. dollar-British pound exchange rate was 4.445%. ISCC will continue to review annually the foreign exchange risk factor.

[11] 15 U.S.C. § 78q–1 (1988).

[12] 17 CFR 200.30–3(a)(12) (1995).

[Release No. 34–37387; File No. SR–NASD–96–27]

Self-Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change by the National Association of Securities Dealers, Inc. Relating to an Interim Extension of the OTC Bulletin Board® Service through December 31, 1996

June 28, 1996.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''), 15 U.S.C. 78s(b)(1), notice is hereby given that on June 28, 1996 the National Association of Securities Dealers, Inc. (''NASD'' or ''Association'') filed with the Securities and Exchange Commission (''Commission'' or ''SEC'') the proposed rule change as described in Items I. II, and III below, which Items have been prepared by the NASD. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons and is simultaneously approving the proposal.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

On June 1, 1990, the NASD, through a subsidiary corporation, initiated operation of the OTC Bulletin Board Service (''OTCBB Service'' or ''Service'') in accord with the Commission's approval of File No. SR–NASD–88–19, as amended.[1] The OTCBB Service provides a real-time quotation medium that NASD member firms can elect to use to enter, update, and retrieve quotation information (including unpriced indications of interest) for securities traded over-the-counter that are not listed on The Nasdaq Stock Market℠ nor on a registered national securities exchange (collectively referred to as ''OTC Equities'').[2] Essentially, the Service supports NASD members' market making in OTC Equities through authorized Nasdaq Workstation® units. Real-time access to quotation information captured in the Service is available to subscribers of Level 2/3 Nasdaq service as well as subscribers of vendor-sponsored services that now carry OTCBB Service data. The Service is currently operating under an interim approval that expires on June 30, 1996.[3]

The NASD hereby files this proposed rule change, pursuant to Section 19(b)(1) of the Act and Rule 19b-4 thereunder, to obtain authorization for an interim extension of the Service through December 31, 1996. During this interval, there will be no material change in the OTCBB Service's operational features, absent Commission approval of a corresponding Rule 19b-4 filing.

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 NASD included statements concerning the purpose of and basis for the proposed rule change and discussed any comments is received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The NASD 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

1. Purpose

The purpose of this filing is to ensure continuity in the operation of the OTCBB Service while the Commission considers an earlier NASD rule filing (File No. SR–NASD–92–7 that requested permanent approval of the Service.[4] For the month ending May, 1996, the Service reflected the market positions of 407 NASD member firms displaying quotations/indications of interest in approximately 5,514, OTC Equities.

During the proposed extension, unregistered foreign securities and American Depositary Receipts (collectively, ''Foreign Equity Securities'') will remain subject to the twice-daily, update limitation that traces back to the Commission's original approval of the OTCBB Service's operation. As a result, all priced bids/offers displayed in the Service for unregistered Foreign Equity Securities will remain indicative.

In conjunction with the launch of the Service in 1990, the NASD implemented a filing requirement (currently under NASD Rule 6740) and review procedures to verify member firms' compliance with Rule 15c2–11 under the Act. During the proposed extension, this review process will continue to be an important component of the NSAD's self-regulatory oversight of broker-dealers' market making in OTC Equities. The NASD also expects to work closely with the Commission staff in developing further enhancements to the Service, including those related to the market structure requirements mandated by the Securities Enforcement Remedies and Penny Stock Reform Act of 1990 (''Reform Act''), particularly Section 17B of the Act.[5] The NASD notes that implementation of the Reform Act entails Commission rulemaking in several areas, including the development of mechanisms for gathering and disseminating reliable quotation/transaction information for ''penny stocks.''

2. Statutory Basis

The NASD believes that this proposed rule change is consistent with Sections 11A(a)(1), 15A(b)(6) and (11), and Section 17B of the Act. Section 11A(a)(1) sets forth the Congressional findings and policy goals respecting operational enhancements to the securities markets. Basically, the Congress found that new data processing and communications techniques should be applied to improve the efficiency of market operations, broaden the distribution of market information, and foster competition among market participants. Section 15A(b)(6) requires, among other things, that the NADS's rules promote just and equitable principles of trade, facilitate securities transactions, and protect public investors. Subsection (11) thereunder authorizes the NASD to adopt rules governing the form and content of quotations for securities traded over-the-counter for the purposes of producing fair and informative quotations, preventing misleading quotations, and promoting orderly procedures for collecting and disseminating quotations. Finally, Section 17B contains Congressional findings and directives respecting the collection and distribution of quotation information on low-priced equity

[1] Securities Exchange Act Release No. 27975 (May 1, 1990), 55 FR 19124.

[2] With the Commission's approval of File No. SR–NASD–93–24, the universe of securities eligible for quotation in the OTCBB now includes certain equities listed on regional stock exchanges that do not qualify of dissemination of transaction reports via the facilities of the Consolidated Tape Association.

[3] Securities Exchange Act Release No. 36292 (September 28, 1995), 60 FR 52241.

[4] Securities Exchange Act Release No. 30766 (June 1, 1992), 57 FR 24281.

[5] On November 24, 1992, the NASD filed an application with the Commission for interim designation of the Service as an automated quotation system for penny stocks, pursuant to Section 17B(b) of the Act. On December 30, 1992, the Commission granted Qualifying Electronic Quotation System (''QEQS'') status for the Service for purposes of certain penny stock rules that become effective on January 1, 1993. On August 26, 1993, the Commission granted the NASD's request for an extension of QEQS status until such time as the OTCBB meets the statutory requirements of Section 17B(b)(2).

securities that are neither Nasdaq nor exchange-listed.

The NASD believes the extension of the Service through December 31, 1996 is fully consistent with the foregoing provisions of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The NASD believes that the rule change will not result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The NASD requests that the Commission find good cause, pursuant to Section 19(b)(2) of the Act, for approving the proposed rule change prior to the 30th day after its publication in the Federal Register to avoid any interruption of the Service. The current authorization for the Service extends through June 30, 1996. Hence, it is imperative that the Commission approve the instant filing on or before that date. Otherwise, the NASD will be required to suspend operation of the Service pending Commission action on the proposed extension.

The NASD believes that accelerated approval is appropriate to ensure continuity in the Service's operation pending a determination on permanent status for the Service, as requested in File No. SR–NASD–92–7. Continued operation of the Service will ensure the availability of an electronic quotation medium to support member firms' market making in approximately 5,514 OTC Equities and the widespread dissemination of quotation information on these securities. The Service's operation also expedites price discovery and facilitates the execution of customer orders at the best available price. From a regulatory standpoint, the NASD's capture of quotation data from participing market makers supplements the transctional data now reported by member firms pursuant to NASD Rule 6600.

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, N.W., Washington, D.C. 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 Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to the file number in the caption above and should be submitted by: July 30, 1996.

V. Commission's Findings and Order Granting Accelerated Approval

The Commission finds that approval of the proposed rule change is consistent with the Act and the rules and regulations thereunder, and in particular with the requirements of Section 15A(b)(11) of the Act, which provides that the rules of the NASD relating to quotations must be designed to produce fair and informative quotations, prevent ficititious or misleading quotations and promote orderly procedures for collecting, distributing, and publishing quotations.

The Commission finds good cause for approving the proposed rule change prior to the 30th day after the date of publishing notice of the filing thereof. The Commission finds that approval of this proposed rule change to continue operation of the pilot program is customers' orders at the best available price. Additionally, continued operation of the Service will materially assist the NASD's surveillance of trading in OTC Equities that are quoted in the Service, including certain non-Tape B securities that are listed on regional exchanges and quoted in the Service.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change be, and hereby is, approved for an interim period through December 31, 1996.

For the Commission, by the Division of Market Regulation, pusuant to delegated authority.[6]

Jonathan G. Katz,

Secretary.

[FR Doc. 96–17351 Filed 7–8–96; 8:45 am]

BILLING CODE 8010–01–M

[6] 17 CFR 200.30–3(a)(12).

[Release No. 34–37385; File No. SR–PSE–96–16]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Pacific Stock Exchange, Inc. Relating to Listing and Trading Guidelines for Municipal Bonds

June 28, 1996.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''), 15 U.S.C. § 78s(b)(1), notice is hereby given that on June 5, 1996, the Pacific Stock Exchange, Inc. (''PSE'' 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 self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The PSE proposes to adopt on a permanent basis rules for the listing and trading of municipal bonds.

The text of the proposed rule change is available at the Office of the Secretary, PSE 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 PSE 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 PSE 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

1. Purpose

On March 7, 1994, the Commission approved an Exchange pilot program providing for the listing and trading of ''municipal securities,'' as defined in Section 3(a)(29) of the Act (''pilot program'')[1] The Exchange now

[1] *See* Securities Exchange Act Release No. 33721 (March 7, 1994), 59 FR 11636 (March 11, 1994). On July 5, 1994, the Commission approved a 120-day extension to the Exchange's Municipal Bond Trading Pilot Program. *See* Securities Exchange Act Release No. 34317 (July 5, 1994), 59 FR 35546 (July

Continued

proposes to adopt this municipal securities pilot program on a permanent basis.

Under the pilot program, a municipal security may be eligible for Exchange listing provided it is rated as investment grade by at least one nationally recognized rating service, and satisfies the Exchange's distribution criteria for bonds of issuers whose corporate securities are not listed on the Exchange, *i.e.*, the size of issue must be at least $20 million principal amount/aggregate market value, with at least 100 holders. In addition, the Exchange may consider such other information as it deems necessary to evaluate the appropriateness of the issue for exchange trading, including the financing structure and/or arrangement of the issuer.

Any municipal securities listed by the Exchange must be assigned to a specialist and traded in accordance with all PSE regulations otherwise applicable to the trading of securities listed on the Exchange. As with corporate bonds, trade reports and quotation information for municipal securities will be disseminated over Network B. However, to ensure uniformity of practice within the securities industry, proposed Rule 5.13(i) provides that all aspects of the trade reconciliation process, including comparison, settlement and clearing will be governed by the applicable requirements of the Municipal Securities Rulemaking Board (''MSRB'').[2]

Under the pilot program, any purchase or sale of a municipal security shall be exempt from the provisions of the Exchange's off-board trading rules.[3] In addition pilot program is not intended to otherwise alter the existing regulatory framework and oversight applicable to municipal securities trading.[4] Finally, a municipal security would be subject to delisting in the event it were no longer rated as investment grade by a nationally recognized rating service.

To accommodate the listing of municipal securities, the PSE proposes to apply the same rules and conditions of the pilot program, as noted above, on a permanent basis. In addition, the Exchange proposes to adopt the following rules on a permanent basis: Rule 3.2(e)(3) (basic listing requirements); Rule 3.5(d)(5) (maintenance requirements); Rule 5.13(i) (comparance, settlement, and clearance); and Rule 5.46(xv) (exemption to offboard trading requirements). The Exchange proposes that any municipal security that it lists be assigned to a specialist and traded in accordance with all PSE regulations otherwise applicable to the trading of securities on the Equity Floors of the Exchange.[5] Finally, the Exchange represents that it will require that its members who trade municipal bonds listed on the Exchange will have an adequate understanding of the tax implication of the trading of such bonds.

2. Statutory Basis

The Exchange believes 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 and to promote just and equitable principles of trade, and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes the proposed rule change will impose no burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the publication of this notice in the Federal Register or within such other 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 the 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, N.W., Washington, D.C. 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 at the Commission's Public Reference Section, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of such filing will also be available for inspection and copying at the principal office of the PSE. All submissions should refer to File No. SR–PSE–96–16 and should be submitted by: July 30, 1996.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[6]

Jonathan G. Katz,

Secretary.

[FR Doc. 96–17353 Filed 7–8–96; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–37391; File No. SR–PSE–96–21]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Pacific Stock Exchange, Inc., Relating to the Liability of the Exchange and its Governors, Officers, and Agents

July 1, 1996.

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 June 17, 1996, the Pacific Stock Exchange, Inc. (''PSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule

12, 1994). The pilot program expired in November 1994.

[2] MSRB Rule G–3 provides specific qualification requirements for municipal securities principals and representatives. In light of the PSE's qualification requirements for specialists, the Exchange believes it is appropriate for the PSE to rely on these requirements for its specialists in lieu of the Rule G–3 standards. It is important, however, that any specialist selected by the PSE for a listed municipal security be familiar with the characteristics of municipal securities.

[3] *See* Rule 5.46.

[4] The National Association of Securities Dealers (''NASD'') has the authority to enforce the MSRB rules. The Exchange notes that it will also be responsible for enforcing MSRB rules for the listed municipal securities. The PSE's enforcement in this regard will not preempt or limit in any manner the NASD's authority to act in this area.

[5] To date, the Exchange has not listed or traded any municipal securities under the pilot program.

[6] 17 CFR 200.30–3(a)(12) (1994).

[1] 15 U.S.C. § 78s(b)(1) (1988).

[2] 17 CFR 240.19b–4

change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The PSE, pursuant to Rule 19b–4 of the Act, proposes to adopt new provisions pertaining to the liability of the Exchange and to amend an existing provision. Specifically, the PSE proposes to adopt: new Rule 13.2, *Liability of Exchange,* which clarifies and broadens the existing limitations on the Exchange's liability; new Rule 13.3, *Legal Proceedings Against Exchange Governors, Officers, Employees or Agents,* which prohibits members from instituting certain types of legal proceedings against Exchange officials; and new Rule 13.4, *Exchange's Cost of Defending Legal Proceedings,* which provides for the recovery of the Exchange's defense costs in certain circumstances. In addition, the PSE proposes to amend Rule 6.59, *Liability of Exchange for Actions of Order Book Officials,* to clarify its purposes and to provide a reference to the new provisions in Rule 13.

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 self-regulatory organization 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 self-regulatory organization 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

1. Purpose

Liability of Exchange

The principal rule concerning Exchange liability is contained in Article VI, Section 6 of the PSE Constitution. Article VI, Section 6 provides that the Exchange is not liable to members for damages arising out of the use or enjoyment of Exchange facilities in the conduct of their business.

New Rule 13.2(a)[3] clarifies that, except as otherwise expressly provided in the rules of the Exchange, neither the Exchange nor its Governors, officers, committee members, employees, or agents shall be liable to members or their associated persons except where the Exchange's liability is attributable to willful misconduct, gross negligence, bad faith, fraud, or criminal acts. In addition, new Rule 13.2(a) clarifies that the limitation of the Exchange's liability includes interruption, failure or unavailability of Exchange facilities or services.

New Rule 13.2(a)[4] also adds language which limits the Exchange's liability for errors, omissions, or delays in calculating or disseminating various kinds of data relating to current or closing index values, reports of transactions or quotations for options or other securities, and further provides that the Exchange does not warrant the results obtained by any person or entity relying on data transmitted by or on behalf of the Exchange or any designated reporting authority. New Rule 13.2(a)[5] states that its provisions are in addition to, and do not limit, the provisions of the PSE Constitution, Article VI, Section 6. Lastly, paragraphs (b) and (c) of new Rule 13.2[6] describe the monetary limits on the Exchange's liability with respect to the Exchange's order routing systems, electronic book, and automatic execution systems.[7]

Legal Proceedings Against Exchange Governors, Officers, Employees or Agents

New Rule 13.3[8] prohibits a member or associated person from instituting a lawsuit or any other type of legal proceeding against any Governor, officer, employee, agent, or other official of the Exchange or any of its subsidiaries based on actions taken or omitted to be taken while such person is acting on Exchange business or the business of any of its subsidiaries. Rule 13.3, however, does not apply where private rights of action under the federal securities laws exist, to appeals of disciplinary actions, to other actions by the Exchange as provided for in its rules, and, with respect to the Governors of the Exchange, to the extent such action or omission is inconsistent with the Exchange's Certificate of Incorporation.

The Exchange notes that new Rule 13.3 does not prohibit a member from suing the Exchange as a result of the actions of these individuals; rather it merely prohibits suits against the person in his or her individual capacity. According to the PSE, the purpose of disallowing lawsuits or other legal proceedings against Exchange officials or agents when they are acting on Exchange business is to eliminate the potential exposure to personal liability of such persons which impairs their ability to perform their duties.

Exchange's Costs of Defending Legal Proceedings

New Rule 13.4[9] requires a member or associated person who fails to prevail in a legal proceeding instituted by that person against the Exchange or other specified persons, and related to the business of the Exchange, to pay to the Exchange all reasonable expenses, including attorney's fees, incurred by the Exchange in its defense of such proceeding. The requirement would apply only where the costs exceed fifty thousand dollars ($50,000).

According to the PSE, this provision is intended to discourage unfounded, vexatious litigation against the Exchange where the Exchange's costs are significant, without having an undue chilling effect on legitimate claims of members. The proposed rule would

[3] The PSE notes that new Rule 13.2(a) is based on Chicago Stock Exchange (''CHX'') Article I, Rule 18(a) and the proposed rule changes filed by the Chicago Board Options Exchange (''CBOE'') to Rule 6.7(a). *See* Securities Exchange Act Release No. 36863 (February 20, 1996), 61 FR 7285 (February 27, 1996) (File No. SR–CBOE–96–02).

[4] The PSE notes that this language to new Rule 13.2(a) is based on CBOE Rule 24.12

[5] The PSE notes that this aspect of new rule 13.2(a) is based on CHX Article 1, Rule 18(b).

[6] The PSE notes that new Rules 13.2(b) and (c) are based on CBOE Rules 6.7(b) and (c).

[7] Under new Rule 13.2(b), the PSE's liability with respect to the Exchange's order routing systems, electronic book, and automatic execution systems is limited to the larger of any recovery obtained by the Exchange under any applicable insurance or: (i) $100,000 as to any claim or series of claims made by a single member on a single day; (ii) $250,000 as to all claims by all members on any single trading day; and (iii) $500,000 as to all claims, in the aggregate, by all members in any calendar month.

Under new Rule 13.2(c), if all of the claims arising out of the use or enjoyment of the facilities afforded by the Exchange cannot be fully satisfied because in the aggregate they exceed the applicable maximum amount of liability provided for in paragraph (b), the maximum amount will be allocated based on the proportion that each claim bears to the sum of all such claims.

[8] The PSE notes that new Rule 13.3 is based on CHX Article I, Rule 17 and the proposed rule changes filed by the CBOE to Rule 6.7A. *See* Securities Exchange Act Release No. 36863, *supra* note 3.

[9] The PSE notes that new Rule 13.4 is based on CHX Article 1, Rule 18(c) and the proposed rule changes filed by the CBOE to Rule 2.24. *See* Securities Exchange Act Release No. 36863, *supra* note 3.

apply to lawsuits or other legal proceedings that might be instituted by members against the Exchange or to any of its Governors, officers, committee members, employees, or agents. This provision, however, would not apply to disciplinary actions, to administrative appeals of Exchange actions, or to any specific instance where the Board of Governors has granted a waiver of this rule.

Liability of Exchange for Actions of Order Book Officials

Current Rule 6.59(a) and (g) are being amended for clarification purposes.[10] Rule 6.59 is also adding a reference to the new provisions in Rule 13.

2. Statutory Basis

The PSE believes that the proposed rule changes are consistent with Section 6(b)(5) of the Act in that, by limiting the liability of the Exchange and its Governors, officers, employees, and agents, by precluding certain types of legal actions by members against such persons individually, and by discouraging frivolous lawsuits against the Exchange, it will reduce the costs of the Exchange in responding to claims and lawsuits, thereby permitting the resources of the Exchange to be better utilized for promoting just and equitable principles of trade and for protecting investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The self-regulatory organization does not believe that the proposed rule change will impose any inappropriate 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 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 the 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, N.W., Washington, D.C. 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 at the Commission's Public Reference Section, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of such filing also will be available for inspection and copying at the principal office of the PSE. All submissions should refer to File No. SR–PSE–96–21 and should be submitted by July 30, 1996.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[11]

Jonathan G. Katz,

Secretary.

[FR Doc. 96–17448 Filed 7–8–96; 8:45 am]

BILLING CODE 8010–01–M

[10] The PSE notes that the amendments are based on CBOE Rules 7.11(b)(1) and 7.11(e), respectively.

[11] 17 CFR 200.30–3(a)(12).

[Release No. 34–37389; File No. SR–Phlx–96–15]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change and Amendment No. 1 Thereto by the Philadelphia Stock Exchange, Inc. Relating to an Amendment to the PHLX's Schedule of Fees and Charges

July 1, 1996.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on May 24, 1996 the Philadelphia Stock Exchange, Inc. (''PHLX'' 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 self-regulatory organization. On June 24, 1996, the PHLX filed Amendment No. 1 to its proposal.[2] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The PHLX, pursuant to Rule 19b–4 of the Act, submits a proposed rule change amending the PHLX's Schedule of Fees and Charges respecting the charges for non-exchange sponsored securities execution equipment[3] operated by the PHLX members on the PHLX equity floor. The proposal would rescind the existing monthly fee of $250.00 assessed each member or member organization for each non-exchange sponsored securities execution machine operated by the member or member organization on the PHLX equity trading floor as well as the credits previously offered against such fees, and substitutes a securities execution equipment registration fee of $300.00 per machine for the period July 1, 1996 through December 31, 1996.[4] Deletions are in brackets:

Membership Dues or Foreign Currency User Fees [*]—$1,000.00 semiannually.

Application Fee—$200.00.

Initiation Fee—Members, Participants, and Approved Lessors—$1500.00.

Transfer Fee—$300.00.

[1] 15 U.S.C. 78s(b)(1).

[2] In Amendment No. 1, the PHLX deleted language that the fee imposed on PHLX members or member organizations for non-exchange sponsored securities execution equipment used on the PHLX equity trading floor conforms to the fee charged for such equipment used on the equity options trading floor; clarified that trades previously counted towards eligibility for credits against the previously imposed monthly charges for securities execution equipment need not have been cleared through SCCP to have qualified for the credit, only executed on the PHLX; and clarified that PHLX members or member organizations will be assessed $300.00 for the period July 1, 1996 through December 31, 1996 for each non-exchange sponsored securities execution machine operated on the PHLX equity trading floor. *See* Letter from Murray L. Ross, Vice President and Secretary, PHLX, to George A. Villasana, Attorney , Division of Market Regulation, SEC, dated June 21, 1996.

[3] Securities execution equipment refers to machines that route order flow to other marketplaces, such as Designated Order Turnaround (''DOT'') machines, Instinet terminals, and other computers configured for securities execution and order delivery capabilities.

[4] *See* Amendment No. 1, *supra* note 2.

According to the Exchange, its Board of Governors has not yet determined the amount of fees to be charged for such equipment after December 31, 1996. Telephone conversation on June 19, 1996 between Murray L. Ross, Vice President and Secretary, PHLX, and George A. Villasana, Attorney, Division of Market Regulation, SEC.

[*] An exemption from foreign currency user fees is extended to PHLX members also holding title to a foreign currency options participation.

Trading Post/Booth—$375.00 quarterly.

Floor Facility Fees—$187.50 quarterly.

Direct Wire to Floor—$60.00 quarterly.

Telephone System Line Extensions—$22.50 monthly/per extension.

Execution Services/Communication Charge—$200.00 monthly.

[Stock Execution Machine *** (Equity Floor)—$250.00 monthly].

Stock Execution Machine Registration Fee [(Option Floor)]—$300.00 per unit.

Equity, Option or FCO Transmission charge—$750.00 monthly.

Quotron Equipment—$225.00 monthly.

Instinet, Reuters Eqiupment—cost pass thru.

FCO pricing tape—$600.00.

Option Report service: New York—$600.00; Chicago—$800.00.

Examinations Fee**—$1,000.00 monthly.

Registered Representative Registration:

Initial—$10.00.

Maintenance—$10.00 annual.

Transfer—$10.00.

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 PHLX 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 self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

*** [$250 credit on fees charged on each stock execution machine by any member firm for each 2,500 trades such member executed on the PHLX equity floor in a non-specialist account is applicable.]

** This fee is applicable to member/participant organizations for which the PHLX is the DEA. The following organizations are exempt: (1) inactive organizations; (2) organizations operating from the PHLX trading floor; (3) organizations for any month where they incur transaction or clearing fees charges directly by the Exchange or by its registered subsidiary, provided that the fees exceed the examinations fee for that month; and (4) organizations affiliated with an organization exempt from this fee due to the second or third category. Affiliation includes an organization that is a wholly owned subsidiary of, or by under common control with, an ''exempt'' member or participant organization. An inactive organization is one which had no securities transaction revenue, as determined by semi-annual FOCUS reports, as long as the organization continues to have no such revenue each month.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Since 1990, the Exchange has imposed on each member or member organization a monthly fee of $250.00 for each non-exchange sponsored securities execution machine the member or member organization operates on the PHLX equity trading floor.[5] Since April 1994, the PHLX has provided a monthly credit equal to 50% of the fees charged members and member organizations for each of these machines for every 2,500 trades executed by such member on the PHLX equity floor in a non-specialist account.[6] This credit was not authorized to exceed 50% of the total securities execution machine billing charges per member operating such machine.[7] Subsequently, however, the credit was authorized to offset up to 100% of such fees.[8]

This proposal rescinds the existing monthly fee of $250.00 assessed on each PHLX member of member organization for each non-exchange sponsored securities execution machine on the PHLX equity trading floor and the related credit scheme, and imposes on each PHLX member of member organization, for the period July 1, 1996 through December 31, 1996, a registration fee of $300.00[9] for each non-exchange sponsored securities execution machine operated on the PHLX equity trading floor.[10]

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act[11] in general and furthers the objectives of Section 6(b)(4)[12] in particular in that it provides for the equitable allocation of reasonable dues, fees, and other charges among the Exchange's members and other persons using its facilities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change constitutes or changes a due, fee, or other charge imposed by the Exchange and, therefore, has become effective pursuant to Section 19(b)(3)(A) of the Act[13] and subparagraph (e) of Rule 19b–4 thereunder.[14]

At any time within sixty days of the filing of such proposed 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, N.W., Washington, D.C. 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 at the Commission's Public Reference Section, 450 Fifth Street, N.W.,

[5] *See* Securities Exchange Act Release No. 28212 (July 17, 1990), 55 FR 30065 (July 24, 1990) (order approving File No. SR–PHLX–90–15).

[6] *See* Securities Exchange Act Release No. 33954 (Apr. 21, 1994), 59 FR 22191 (Apr. 29, 1994) (order approving File No. SR–PHLX–94–19).

[7] *Id.*

[8] *See* Securities Exchange Act Release No. 36682 (Jan. 4, 1996), 61 FR 1200 (Jan. 17, 1996) (order approving File No. SR–PHLX–95–89).

The Exchange advised the Commission that trades previously counted towards eligibility for credits against the previously imposed monthly charges for such stock execution equipment need not have been cleared through SCCP to have qualified for the credit; the trades needed-merely to be executed on the PHLX. *See* Amendment No. 1, *supra* note 2.

[9] A registration fee of $300 is presently imposed on member or member organizations for no-change sponsored securities execution equipment operated by a PHLX member of member organization on the PHLX equity options trading floor for the period Sept. 1, 1995 through Dec. 31, 1996. Securities Exchange Act Release No. 36198 (Sept. 7, 1995), 60 FR 47639 (Sept. 13, 1995) (order approving File No. SR–PHLX–95–64).

[10] *See infra* note 3.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(4).

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4.

Washington, D.C. 20549. Copies of such filing also will be available for inspection and copying at the principal office of the Philadelphia Stock Exchange. All submissions should refer to File No. SR–PHLX–96–15 and should be submitted by July 30, 1996.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[15]

Jonathan G. Katz,

Secretary.

[FR Doc. 96–17355 Filed 7–8–96; 8:45 am]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster Loan Area #2867]

Pennsylvania; Declaration of Disaster Loan Area

As a result of the President's major disaster declaration on June 18, 1996, I find that Bucks County in the State of Pennsylvania constitutes a disaster area due to damages caused by flooding which occurred on June 12, 1996. Applications for loans for physical damages may be filed until the close of business on August 17, 1996, and for loans for economic injury until the close of business on March 18, 1997 at the address listed below:

U.S. Small Business Administration, Disaster Area 1 Office, 360 Rainbow Blvd. South, 3rd Fl., Niagara Falls, NY 14303 or other locally announced locations. In addition, applications for economic injury loans from small businesses located in the following contiguous counties may be filed until the specified date at the above location: Lehigh, Montgomery, Northampton, and Philadelphia Counties in Pennsylvania, and Burlington, Hunterdon, Mercer, and Warren Counties in New Jersey.

Interest rates are:

	Percent
For Physical Damage:	
Homeowners with credit available elsewhere	7.625
Homeowners without credit available elsewhere	3.875
Businesses with credit available elsewhere	8.000
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

[15] 17 CFR 200.30–3(a)(12).

The number assigned to this disaster for physical damage is 286706. For economic injury the numbers are 894700 for Pennsylvania, and 894800 for New Jersey.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: June 27, 1996.

Allan I. Hoberman,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 96–17401 Filed 7–8–96; 8:45 am]

BILLING CODE 8025–01–P

[Declaration of Disaster Loan Area #2859; Amendment #2]

West Virginia; Declaration of Disaster Loan Area

In accordance with a notice from the Federal Emergency Management Agency, effective June 10, 1996, the above-numbered Declaration is hereby amended to establish the incident period for this disaster as beginning on May 15, 1996 and continuing through June 10, 1996.

All other information remains the same, i.e., the termination date for filing applications for physical damage is July 22, 1996, and for loans for economic injury the deadline is February 24, 1997.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: June 28, 1996.

Allan I. Hoberman,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 96–17400 Filed 7–8–96; 8:45 am]

BILLING CODE 8025–01–P

U.S. SMALL BUSINESS ADMINISTRATION

Atlanta District Advisory Council Meeting; Public Meeting

The U.S. Small Business Administration, Atlanta District Advisory Council will hold a public meeting on Friday, July 12, 1996 at 7:30 a.m. at the Wyndham Garden Hotels, 125 10th Street, NE., Atlanta, GA 30309 to discuss 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. Laura A. Brown, District Director, U.S. Small Business Administration, 1720 Peachtree Road, NE., Suite 600, Atlanta, GA 30309, (404) 347–4147 extension 46.

Dated: July 1, 1996.

Michael P. Novelli,

Director, Office of Advisory Council.

[FR Doc. 96–17335 Filed 7–8–96; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice #2411]

United States International Telecommunications Advisory Committee Telecommunications Development Sector (ITAC–D) Group; Meeting Notice

The Department of State announces that the United States International Telecommunications Advisory Committee (ITAC) Telecommunications Development Sector (ITAC–D) Group will meet over the next two months to prepare for the upcoming ITU–D Working Parties of Study Groups 1 and 2 to be held in Geneva, September 10–19, 1966. The dates, times and room number of the meetings are outlined below:

Friday, July 26, 10:00–12:00 noon, Room 2533A.

Thursday, August 1, 10:00–12:00 noon, Room 2533A.

Friday, August 9, 10:00–12:00 noon, Room 2533A.

Friday, August 30, 10:00–12:00 noon, Room 2533A.

Friday, September 6, 10:00–12:00 noon, Room 2533A.

The agenda for the ITAC–D Group meeting will include (1) U.S. preparations for the Working Parties meetings of ITU–D Study Group 1 (Telecommunication Development Strategies and Policies) and Study Group 2 (Development, Harmonization, Management and Maintenance of Telecommunication Networks and Services), and (2) a review of U.S. contributions for that meeting.

Members of the General Public may attend the meetings and join in the discussions, subject to the instructions of the chair. Admittance of public members will be limited to the seating available. In this regard, entrance to the Department of State is controlled.

Questions regarding the meeting may be addressed to Ms. Doreen McGirr at 202–647–0201. If you wish to attend please send a fax to 202–647–7407 no later than 5 days before the scheduled meetings. Please include your name, Social Security number and date of birth. One of the following valid photo ID's will be required for admittance: U.S. driver's license with picture, U.S.

passport, U.S. government ID (company ID's are no longer accepted by Diplomatic Security). Enter from the ''C'' Street Main Lobby.

Dated: July 2, 1996.

Doreen F. McGirr,

Chair, U.S. ITAC for Telecommunications Development.

[FR Doc. 96–17336 Filed 7–8–96; 8:45 am]

BILLING CODE 4710–45–M

TENNESSEE VALLEY AUTHORITY

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Tennessee Valley Authority (Meeting No. 1486).

TIME AND DATE: 9 a.m. (CDT), July 11, 1996.

PLACE: Choctaw County Courthouse, East Quinn Street, Ackerman, Mississippi.

STATUS: Open.

Agenda

Approval of minutes of meeting held on June 19, 1996.

New Business

C—Energy

C1. Delegation of Authority to the Senior Vice President, Transmission/ Power Supply Group, or a designated representative, to purchase the output of approximately 400 megawatts of base load power, under long term arrangements from the Mississippi Lignite Project, which is being developed by CRSS Inc. and Phillips Coal Company.

FOR MORE INFORMATION: Please call TVA Public Relations at (423) 632–6000, Knoxville, Tennessee. Information is also available at TVA's Washington Office (202) 898–2999.

Dated: July 3, 1996

Edward S. Christenbury,

General Counsel and Secretary.

[FR Doc. 96–17538 Filed 7–5–96; 8:45 am]

BILLING CODE 8120–08–M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Notice 96–20]

Senior Executive Service Performance Review Boards (PRB) Membership

AGENCY: Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: DOT publishes the names of the persons selected to serve on the various Departmental Performance Review Boards (PRB) established by DOT under the Civil Service Reform Act.

FOR FURTHER INFORMATION CONTACT: Glenda M. Tate, Director of Personnel and Executive Secretary, DOT Executive Resources Board, (202) 366–4088.

SUPPLEMENTARY INFORMATION: Title 5 U.S.C. 4312 requires that each agency implement a performance appraisal system making senior executives accountable for organizational and individual goal accomplishment. As part of this system, 5 U.S.C. 4314(c) requires each agency to establish one or more PRBs, the function of which is to review and evaluate the initial appraisal of a senior executive's performance by the supervisor and to make recommendations to the final rating authority relative to the performance of the senior executive.

The persons named below have been selected to serve on one or more Departmental PRBs.

Issued in Washington, D.C., on July 2, 1996.

Melissa J. Spillenkothen,

Assistant Secretary for Administration.

Department of Transportation Nominations for Performance Review Boards Fiscal Year 1996 Performance Appraisal Cycle

Office of the Secretary

John Taylor, Director, Office of Security and Administrative Management, Office of the Secretary.

Richard B. Chapman, Director, Information Technology Operations, Transportation Administrative Service Center.

Patricia A. Prosperi, Director, Information Services, Transportation Administrative Service Center.

Douglas Leister, Executive Assistant, Office of the Secretary.

Donald Trilling, Director, Office of Environment, Energy, & Safety, Office of the Secretary.

Eileen T. Powell, Director, Office of Financial Management, Office of the Secretary.

Paul Geier, Assistant General Counsel for Litigation, Office of the Secretary.

Thomas Herlihy, Assistant General Counsel for Legislation, Office of the Secretary.

Samuel Podberesky, Assistant General Counsel for Aviation Enforcement and Proceedings, Office of the Secretary.

Dorrie Y. Aldrich, Associate Administrator for Administration (proposed), Federal Transit Administration.

Luz A. Hopewell, Director, Office of Small and Disadvantaged Business Utilization, Office of the Secretary.

Office of Inspector General

Eileen Boyd, Assistant Inspector General for Civil & Administrative Remedies, Department of Health and Human Services.

John J. Connors, Deputy Inspector General, Department of Housing and Urban Development.

Judith J. Gordon, Assistant Inspector General for Systems Evaluation, Department of Commerce.

Nancy Hendricks, Assistant Inspector General for Audits, Department of Energy.

Donald Mancuso, Assistant Inspector General for Investigations, Department of Defense.

Steve A. McNamara, Assistant Inspector General for Audit, Department of Education.

Everett Mosley, Deputy Inspector General, Agency for International Development.

Robert S. Terjesen, Assistant Inspector General for Investigations, Department of State.

Joseph R. Willever, Deputy Inspector General, Office of Personnel Management.

United States Coast Guard

RADM William C. Donnell, Chief of Human Resources, United States Coast Guard.

RADM Norman T. Saunders, Chief of Operations, United States Coast Guard.

RADM Alan M. Steinman, Director, Health and Safety Directorate, United States Coast Guard.

RADM Edward J. Barrett, Chief of Systems, United States Coast Guard.

RADM Robert C. North, Director of Acquisition, United States Coast Guard.

RADM John T. Tozzi, Director of Information and Technology, United States Coast Guard.

RADM Paul J. Pluta, Director, Office of Intelligence and Security, United States Coast Guard.

Jerry A. Hawkins, Director, Office of Personnel and Training, Federal Highway Administration.

Diana Zeidel, Deputy Associate Administrator for Administration, Federal Highway Administration.

Richard Chapman, Director, Information Technology Operations, Transportation Administrative Service Center.

Kay Frances Dolan, Director of Human Resource Management, Federal Aviation Administration.

Joan M. Bondareff, Chief Counsel, Maritime Administration.

Federal Highway Administration

George S. Moore, Jr., Associate Administrator for Administration, Federal Highway Administration.

Arthur E. Hamilton, Regional Administrator, Region 7, Kansas City, Missouri, Federal Highway Administration.

Dennis C. Judycki, Associate Administrator for Safety and System Applications, Federal Highway Administration.

Andrew M. Paven, Director of External Communications, Federal Highway Administration.

Christine M. Johnson, Director, ITS Joint Program Office, Federal Highway Administration.

Patricia D. Parrish, Director, Customer Service, Transportation Administrative Service Center.

Federal Railroad Administration

S. Mark Lindsey, Chief Counsel, Federal Railroad Administration.

Sally Hill Cooper, Associate Administrator for Policy and Program Development, Federal Railroad Administration.

Ray Rogers, Associate Administrator for Administration and Finance, Federal Railroad Administration.

James T. McQueen, Associate Administrator for Railroad Development, Federal Railroad Administration.

Philip Olekszyk, Associate Administrator for Safety, Federal Railroad Administration.

Rosalind A. Knapp, Deputy General Counsel, Office of the Secretary.

Judith Burrell, Director, Executive Secretariat, Office of the Secretary.

National Highway Traffic Safety Administration

Donald Bischoff, Associate Administrator for Plans and Policy, National Highway Traffic Safety Administration.

Samuel Dubbin, Chief Counsel, National Highway Traffic Safety Administration.

James Hedlund, Associate Administrator for Traffic Safety Programs, National Highway Traffic Safety Administration.

Dennis Judycki, Associate Administrator for Safety and System Application, Federal Highway Administration.

Jerry Hawkins, Director, Office of Personnel and Training, Federal Highway Administration.

Luz Hopewell, Director, Office of Small and Disadvantaged Business Utilization, Office of the Secretary.

Federal Transit Administration

Rosalind A. Knapp, Deputy General Counsel, Office of the Secretary.

Peter G. Halpin, Director, Office of Congressional Affairs, Office of the Secretary.

James T. McQueen, Associate Administrator for Railroad Development, Federal Railroad Administration.

Charlotte M. Adams, Associate Administrator for Planning, Federal Transit Administration.

Gloria J. Jeff, Associate Administrator for Policy, Federal Highway Administration.

Jerry A. Hawkins, Director, Office of Personnel and Training, Federal Highway Administration.

Kevin E. Heanue, Director, Office of Environment and Planning, Federal Highway Administration.

Maritime Administration

Bruce J. Carlton, Associate Administrator for Policy and International Affairs, Maritime Administration.

James J. Zok, Associate Administrator for Ship Financial Assistance Cargo Preference, Maritime Administration.

Margaret D. Blum, Associate Administrator for Port, Intermodal and Environmental Activities, Maritime Administration.

John L. Mann, Jr., Associate Administrator for Administration, Maritime Administration.

James E. Caponiti, Associate Administrator for National Security, Maritime Administration.

Joan M. Bondareff, Chief Counsel, Maritime Administration.

Sharon (Cher) Brooks, Director, Office of Congressional and Public Affairs, Maritime Administration.

Jerry Hawkins, Director, Office of Personnel and Training, Federal Highway Administration.

Research and Special Programs Administration

Sally Hill Cooper, Associate Administrator for Policy, Federal Railroad Administration.

Beverly Pheto, Director, Office of Budget and Program Performance, Office of the Secretary.

Philip S. Coonley, Director, Office of Administration, Volpe National Transportation Systems Center, Research and Special Programs Administration.

Jane F. Garvey, Deputy Administrator, Federal Highway Administration.

David J. Litman, Director, Acquisition and Grant Management, Office of the Secretary.

Rose A. McMurray, Associate Administrator for Management and Administration, Research and Special Programs Administration.

Patricia D. Parrish, Director, Customer Service, Transportation Administrative Service Center.

Richard Felder, Associate Administrator for Pipeline Safety, Research and Special Programs Administration.

Joseph Kanianthra, Director, Office of Crash Avoidance Research, National Highway Traffic Safety Administration.

Frank F.C. Tung, Deputy Director, Volpe National Transportation Systems Center, Research and Special Programs Administration.

[FR Doc. 96–17416 Filed 7–8–96; 8:45 am]
BILLING CODE 4910–62–P

Federal Aviation Administration

Proposed Advisory Circular 21–SQC, Use of Statistical Quality Control for Product Inspection and Acceptance

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice announces the availability of proposed Advisory Circular (AC) 21–SQC, Use of Statistical Quality Control for Product Inspection and Acceptance, for review and comments. The proposed AC 21–SQC provides information and guidance concerning an acceptable means, but not the only means, of demonstrating compliance with the requirements of the Federal Aviation Regulations Part 21, Certification Procedures for Products and Parts.

DATES: Comments submitted must identify the proposed AC 21–SQC project number, 94–034, and be received by September 6, 1996.

ADDRESSES: Copies of the proposed AC 21–SQC can be obtained from and comments may be returned to the following: Federal Aviation Administration, Policy, Evaluation, and Analysis Branch, AIR–230, Production and Airworthiness Certification Division, Aircraft Certification Service, 800 Independence Avenue, SW., Washington, DC 20591.

FOR FURTHER INFORMATION CONTACT: Policy, Evaluation, and Analysis Branch, AIR–230, Production and Airworthiness Certification Division, Room 815, Aircraft Certification Service, Federal Aviation Administration, 800 Independence Avenue, SW, Washington, DC 20591, (202) 267–8361.

SUPPLEMENTARY INFORMATION:

Background

The proposed AC 21–SQC provides information and guidance to FAA production approval applicants or holders concerning the use of statistical quality control (SQC).

Comments Invited

Interested persons are invited to comment on the proposed AC 21–SQC listed in this notice by submitting such written data, views, or arguments as they desire to the aforementioned specified address. All communications received on or before the closing date for comments specified above will be considered by the Director, Aircraft Certification Service, before issuing the final AC.

Comments received on the proposed AC 21–SQC may be examined before and after the comment closing date in Room 815, FAA headquarters building (FOB–10A), 800 Independence Avenue SW, Washington, DC 20591, between 8:30 a.m. and 4:30 p.m.

Issued in Washington, DC, on July 3, 1996.

Frank P. Paskiewicz,

Acting Manager, Production and Airworthiness Certification Division.

[FR Doc. 96–17419 Filed 7–8–96; 8:45 am]

BILLING CODE 4910–13–M

Federal Railroad Administration

Petition for Waivers of Compliance

In accordance with 49 CFR Sections 211.9, 211.41 and 211.45, notice is hereby given that the Federal Railroad Administration (FRA) has received a request for a waiver of compliance with certain requirements of the Federal safety laws and regulations. The individual petition is described below, including the party seeking relief, the regulatory provisions involved, the nature of the relief being requested and the petitioner's arguments in favor of relief.

3R International

[Docket Numbers F–96–3, RSGM–96–6, LI–96–1, SA–96–3 and PB–96–4]

3R International (3R) requests waivers of compliance with certain provisions of the Federal Railroad Administration (FRA) railroad safety regulations. It is seeking relief from sections of the Railroad Freight Car Safety Standards (49 CFR Part 215) Docket number F–96–1, Railroad Safety Glazing Standards (49 CFR Part 223) Docket number RSGM–96–1, Railroad Locomotive Safety Standards (49 CFR Part 229) Docket number LI–96–1, Railroad Safety Appliance Standards (49 CFR Part 231) Docket number SA–96–3, and Railroad Power Brake and Drawbar Regulations (49 CFR Part 213) Docket number PB–96–4. The relief is being sought in order to place in service what the petitioner describes as the 3R road/rail system. The 3R system was developed and two 3R trains have been operated by the Canadian National Railway in revenue service without incident in Canada for the previous two years.

The 3R road/rail system provides the means to transform a common semi-trailer at little cost for use in a convoy on railway tracks. This adaptation is made by adding at the rear of a semi-trailer or container carrying chassis a second king-pin similar to that used at the front of a semi-trailer. The 3R road/rail system is composed of a control cab unit which is used as a crew station at the front end of the convoy and contains all the electronic controls for the intermodal train, but has no propulsion capability, nor does it have an air compressor. The control cab has a console type control stand with computer screens. Air is supplied by the power units through the main air reservoir pipe which runs through the train and into the cab control unit, where it is supplied to the brake pipe through the 26 L feed valve. A 26 L type air brake with a 30CW controller is located on the console. The control cab unit does have an engine/generator set to provide power for the control system and battery charging. The control cab unit controls the power units remotely by radio, but a hard wire capability is available. It is equipped with two non-driving rail wheel/axle sets and a set of retractable rubber tires for off rail movement. The control cab unit contains a fifth wheel which engages and locks the kingpin of the first semi-trailer in the convoy or a power unit. Subsequent semi-trailers are transported on bogies which contains two rail wheel sets and two fifth wheels for securing the kingpin of the semi-trailers. A power unit is incorporated in the convoy at intervals of eight to ten semi-trailers. For intermodal operation, each power unit can haul seven to eight trailers of 93,500 pounds at 65 mph.

The 3R system allows the assembly of a convoy directly in the yard of a customer and such convoy remains intact until it reaches its destination. Assembling is made on a rail siding which can be accessed by a highway tractor. The train is made up by placing a semi-trailer upon a bogie and locking onto the kingpin, raising the highway wheels and moving the assembled portion of the train a distance sufficient to place each subsequent semi-trailer in the train. A power unit is placed between two semi-trailers and connected by a kingpin at one end to the adjacent bogie's fifth wheel and to the kingpin of the semi-trailer with the power units fifth. A dead weight unit, which contains a standard automatic coupler, is placed as a counter weight at the back end of the last bogie in the train. The coupler allows hauling from the back end with a maximum tractive effort of 50,000 pounds.

3R request for a waiver from the requirements of 49 CFR Part 215 is based upon the fact that the semi-trailer is not a rail car. However, all those parts of the train that are referenced in the regulation, i.e., wheels, trucks, springs, etc. are required to be in compliance, and are contained within the bogies. The bogies are fabricated of steel elements arranged to encompass 2–AAR 6 by 11 cartridge roller bearings and wheel sets. A sub assembly contains 2-fifth wheels which engage the kingpin of the semi-trailers. The sub-assembly is raised by 12 air bags which lift the tires off the ground after the semi-trailer is connected to the bogie. The bogie is equipped with an ABD air brake.

3R request for a waiver from 49 CFR part 223 is related to the glazing material of the control cab. The glazing material is in compliance with the Canadian Transport Commission (CTC) Railway Safety Glazing Regulations. 3R indicates that the front and side facing glazing is in conformity with CTC regulations. It may not be in compliance with FRA glazing standards.

3R request for a waiver from 49 CFR Part 229 is for the control cab and the power units within the train, which are defined in the Locomotive Safety Standard, 49 CFR 229.5(k) as *Locomotives.* The control cab has no propelling motors but has a control stand and the power units have propelling motors designed to move other equipment. The control cab is designed with two front collision posts which will withstand 500,000 pounds each at a height of 30 inches above the underframe. It can also withstand 200,000 pound load compression between front coupler and kingpin without permanent deformation. The power units are placed in the train to provide traction power through a 40 inch wheel set and an axle mounted traction motor. The power unit is designed so that one end rides on and is connected to the adjacent bogie by the kingpin and the other end connects to the king-pin of an adjacent semi-trailer. The power unit contains a 12 cylinder Caterpillar diesel engine driving a Kato traction alternator. The engine is rated at 730 horsepower and the traction

alternator has a continuous capacity 1250 amps, and a 15 minute rating of 1700 amps at a maximum voltage rating of 1250 direct current. The power unit is self contained encompassing all the accessories necessary for a locomotive. The power units also contain a hydraulic driven 2-stage air compressor which provides air for the air brake system and train air for the balloon suspension system of the bogies.

3R request for a waiver from 49 CFR Part 231 and 232 is for the lack of safety appliances and handholds on the bogies, rear counter weight, or semi-trailers in the train. The cab control unit has an automatic front coupler and some safety appliances. Some handholds are applied to the power units. The semi-trailers are connected to the bogies by use of kingpins and fifth wheels commonly found in highway tractor/semi-trailer service. The cab control unit, power units and bogies have no hand brakes per se, but are equipped with a spring loaded parking brake.

The 3R rail system has not been used in the United States. A consist of a cab control unit, a power unit, three containers on chassis (semi-trailers), one dead weight unit, and sufficient bogies to assemble the train was tested by the Association of American Railroads (AAR) at the Transportation Technology Center (TTC) in Pueblo, Colorado, from December 1994 to April 1995. The train was tested according to the specifications of Chapter XI, of the AAR's M–1001, *Manual of Standards and Recommended Practices.* The 3R train performed within Chapter XI performance standards, and indicate the likelihood of safe car performance.

3R's objective in the United States is to allow short line operators to benefit from their value added road/rail transportation system, by transporting on rail, the freight that would be destined to an alternate and less desirable mode of transportation. When the waiver petition was submitted by 3R, two United States short line railroads had shown a strong interest in its road/rail system. Rail America, one of the short lines, would like to operate two road/rail convoys of six power units each with sixty containers. The equipment will operate at approximately 45 mph and haul domestic waste in 82,500 pound containers from inner-city points to suburban waste dumps.

Interested parties are invited to participate in this proceeding by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with this proceeding since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (e.g., Waiver Petition Docket Number LI–96–1) and must be submitted in triplicate to the Docket Clerk, Office of Chief Counsel, Federal Railroad Administration, Nassif Building, 400 Seventh Street, S.W., Washington, D.C. 20590. Communications received within 45 days of the date of publication of this notice will be considered before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) in Room 8201, Nassif Building, 400 Seventh Street, S.W., Washington, D.C. 20590.

Issued in Washington, D.C. on July 2, 1996.

Phil Olekszyk,

Deputy Associate Administrator for Safety Compliance and Program Implementation.

[FR Doc. 96–17455 Filed 7–8–96; 8:45 am]

BILLING CODE 4910–06–P

Petition for Waivers of Compliance

In accordance with 49 CFR Sections 211.9 and 211.41, notice is hereby given that the Federal Railroad Administration (FRA) has received from the De Queen & Eastern Railroad Company, Texas, Oklahoma & Eastern Railroad Company a request for a waiver of compliance with certain requirements of Federal regulations. The petition is described below, including the regulatory provisions involved, the nature of the relief being requested and the petitioner's arguments in favor of relief.

De Queen & Eastern Railroad Company

Texas, Oklahoma & Eastern Railroad Company

[Docket Number SA–96–4]

The De Queen & Eastern Railroad Company; Texas, Oklahoma & Eastern Railroad Company (DQE–TOE) seeks a waiver of compliance from certain sections of 49 CFR Part 231, Railroad Safety Appliance Standards. The DQE–TOE is requesting a permanent waiver of the provisions of 49 CFR Part 231 which requires end ladders. The DQE–TOE wish to remove the end ladders on the subject cars.

The DQE–TOE has 300 high side open top cars for hauling wood chips. Two hundred of these cars are end dump cars, in that the ends when unlocked swing upwards permitting easier unloading of the wood chips.

49 CFR 231.1(e)(3) requires one ''. . . [ladder] on each side, not more than 8 inches from left side of car ''. . .''

The DQE–TOE states that the end ladder ladders serve no useful purpose and are costly to maintain. The end doors are opened by machinery and are constantly being damaged.

The DQE–TOE operates freight service from Perkins, Arkansas to Valliant, Oklahoma, a distance of eighty-six miles one way. Two trains are operated daily for the movement of approximately thirty (30) cars of wood chips in each train.

The DQE–TOE further state that company policy prohibits employees from using these ladders and that the removal of the end ladders would not have an adverse effect on safety.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (e.g., Waiver Petition Docket Number–SA–96–4 and must be submitted in triplicate to the Docket Clerk, Chief Counsel, Federal Railroad Administration, Nassif Building, 400 Seventh Street, S.W., Washington, D.C. 20590. Communications received before August 19, 1996, will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.—5 p.m.) in Room 8201, Nassif Building, 400 Seventh Street S.W., Washington, D.C. 20590.

Issued in Washington, D.C. on July 2, 1996.

Phil Olekszyk,

Deputy Associate Administrator for Safety Compliance and Program Implementation.

[FR Doc. 96–17454 Filed 7–8–96; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF VETERANS AFFAIRS

Veterans' Claims Adjudication Commission; Notice of Public Meeting

The Department of Veterans Affairs (VA), in accordance with Public Law 92–463, gives notice that the Veterans' Claims Adjudication Commission will conduct its eighth public meeting on Tuesday, July 16, and Wednesday, July 17, 1996, at the Department of Veterans Affairs Central Office, 810 Vermont Avenue, NW., Room 230, Washington, DC. The Commission will meet from 8:30 a.m. to 4:30 p.m. on both days.

This public meeting will focus mainly on discussion and consideration of proposed findings, conclusions, and recommendations, which have originated from the Commission's new areas of pursuit.

On July 16, the Commission will begin to discuss and consider proposed findings, conclusions, and recommendations generated from new areas of pursuit including:

- *Strategic Management Planning*—Setting strategic goals and embracing the accelerated development and integrated strategic management process;
- *Adjudication and Appeals Issues*—Redesigning the adjudication and appeals process to make it more functional, fair, and efficient;
- *Disability Compensation Advisory Committee*—Establishing an Advisory Committee which reports to the Secretary of Veterans Affairs regarding disability compensation issues;
- *Annual Report on VA's Disability Compensation Program*—Developing an annual report which provides comprehensive information to be used in the long-term management of the program; and
- *Medical Examinations*—Assessing the military separation examination test to effect changes that will benefit servicemembers and veterans.

At the end of the day, the Commission will receive an update from the Veterans Benefits Administration's Business Process Reengineering (BPR) Team.

On Wednesday, July 17, the Commission will continue to discuss and consider proposed findings, conclusions, and recommendations from new areas of pursuit including:

- *VA Disability Compensation and Commercial Disability Insurance Comparisons*—Consideration of program and administrative practices of commercial insurers for possible adoption or adaptation by VA;
- *Lump Sum Compensation Benefits at Lower Disability Levels*—Revising the payment system to ''free-up'' time and resources so that the needs of more severely disabled veterans could be better served;
- *VA Pension Program/Supplemental Security Income Program Relationship*—Determining the relationship between the VA Pension Program and the Supplemental Security Income Program;
- *VA Pension Reform*—Reform and streamline the Pension Program to reduce the confusion and burden on the veteran and VA;
- *Claims Intake Issues*—Simplifying the application form and claims filing procedures, in addition to developing cooperative strategies with Veterans Service Organizations to encourage the submission of fully supported claims; and
- *Other Relevant Issues*—Issues on which the Commission *will not* take a formal position/make a formal recommendation, such as the lack of closure for VA compensation claims, and reevaluating the purpose of the rating schedule.

The meeting is open to the public; however, no time is allocated for the purpose of receiving oral presentations from the public. The Commission will accept appropriate written comments from interested parties on the subject matter addressed during the meeting. Such comments may be referred to the Commission at the following address: Veterans' Claims Adjudication Commission (20C), U.S. Department of Veterans Affairs, 810 Vermont Ave., NW., Washington, DC 20420.

Additional information concerning this meeting may be obtained by contacting the Commission at (202) 275–2142.

Dated: June 26, 1996.

By Direction of the Secretary.

Heyward Bannister,

Committee Management Officer.

[FR Doc. 96–17365 Filed 7–8–96; 8:45 am]

BILLING CODE 8320–01–M

Advisory Committee on the Readjustment of Vietnam and Other War Veterans, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under Pub. L. 92–463 that a meeting of the Advisory Committee on the Readjustment of Vietnam and Other War Veterans will be held July 25 and 26, 1996. This meeting will be a field meeting conducted primarily at VA facilities in Tacoma and Seattle, Washington. The Committee will also visit the Colville, Lumni and Tulalip Indian Reservations in eastern and central Washington to review the availability of services for area rural and minority veterans. The purpose of the meeting is to provide the Committee a first hand opportunity to review the provision and coordination of VA services for war-related post-traumatic stress disorder (PTSD) and other readjustment difficulties specific to war veterans. For this purpose the Committee will tour facilities, and engage in discussions with VA service providers and veteran consumers.

The meeting on July 25 will begin at 8: a.m. and conclude at 5 p.m. The day's agenda will be conducted concurrently at two different locations. Specifically the Committee will visit the American Lake VA Medical Center and the Tacoma Vet Center. The day's agenda will consist of direct observations of VA readjustment counseling and mental health services with particular attention to the PTSD Clinical Team at the American Lake VA Medical Center. An additional focus for the meeting is continuity of care and clinical follow-up between area VA medical centers and Vet Centers. A separate Committee group will visit the Colville Indian Reservation in Nespelem, Washington to review available services and meet with area veterans.

The meeting on July 26 will begin at 8 a.m. and conclude at 4 p.m. The second day's agenda will also be conducted concurrently at two different locations. The regular agenda will consist of a continuation of direct observations of VA programs and facilities at the Seattle VA Medical Center and Vet Center. Concurrently a separate Committee subgroup will be visiting with local veterans at the Lumni and Tulalip Indian Reservations in Bellingham and Marysville, Washington. In addition to the regular agenda the Committee will conduct a local community forum meeting and group discussion with VA and non-VA officials and service providers, and local veteran representatives regarding the post-war readjustment and service needs of area war veterans. The meeting will be conducted from 5 p.m. to 7 p.m. at the Seattle Vet Center, 2230 Eighth Avenue, Seattle, Washington 98121.

The meeting will be closed from 8 a.m. to 5 p.m. on Thursday, July 25, and from 8 a.m. to 4 p.m. on Friday, July 26, in accordance with the provisions cited in 5 U.S.C. 522b(c)(6) pursuant to subsection 10(d) of the Federal Advisory Committee Act. During this portion of the meeting the Committee will be engaging in discussions with VA clinical service providers and veteran

consumers. The discussions will disclose information of a personal nature for veteran patients which would constitute a clearly unwarranted invasion of personal privacy. The meeting on July 26 from 5 p.m. to 7 p.m. will be open to the public to the seating capacity of the facility.

Anyone having questions concerning the meeting may contact Alfonso R. Batres, Ph.D., M.S.S.W., Director, Readjustment Counseling Service, Department of Veterans Affairs Central Office at (202) 273–8967.

Dated: June 26, 1996.

Heyward Bannister,

Committee Management Officer.

[FR Doc. 96–17364 Filed 7–8–96; 8:45 am]

BILLING CODE 8320–01–M

Federal Register

Tuesday
July 9, 1996

Part II

Environmental Protection Agency

40 CFR Parts 51 and 93

Transportation Conformity Rule Amendments: Flexibility and Streamlining; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 51 and 93

[FRL–5527–8]

RIN 2060–AG16

Transportation Conformity Rule Amendments: Flexibility and Streamlining

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing a more streamlined and flexible transportation conformity rule. The conformity rule requires that transportation plans, programs, and projects conform to state air quality implementation plans (SIPs) and establishes the criteria and procedures for determining whether or not they do. Conformity to a SIP means that transportation activities will not produce new air quality violations, worsen existing violations, or delay timely attainment of national ambient air quality standards.

Since publication of the original rule in November 1993, EPA, the Department of Transportation (DOT), and state and local air and transportation officials have had considerable experience implementing the criteria and procedures in the rule. The changes proposed today are a result of this experience and are intended to make the conformity rule less complex and make it a more effective planning tool. The proposed changes will not result in any change in health and environmental benefits.

This proposed rule would give state and local governments more authority in setting the performance measures used as tests of conformity and more discretion when a transportation plan does not conform to a SIP. The proposal would allow motor vehicle emissions budgets in a submitted SIP to be used to determine conformity instead of the ''build/no-build'' test. Modeling requirements would be tailored for different types of areas, and rural areas would be able to choose among several conformity tests.

DATES: Comments on this action must be submitted on or before September 9, 1996. EPA will conduct one public hearing on this proposal beginning at 10 a.m. on Tuesday, August 6, 1996, in Washington, DC. As described in section XVI. of today's action, the hearing will continue throughout the day until all testimony has been presented.

ADDRESSES: Interested parties may submit written comments (in duplicate, if possible) to: Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, Attention: Docket No. A–96–05, 401 M Street, SW., Washington, DC 20460. (Those desiring notification of receipt of comments must include a self-addressed, stamped postcard.)

The public hearing will be held in Washington, DC, at the Holiday Inn Capitol Hill, 550 C Street, SW., Washington, DC 20024, (202) 479–4000.

Materials relevant to this rulemaking are contained in Public Docket A–96–05 by EPA. The docket is located at the above EPA address in room M–1500 Waterside Mall (ground floor) and may be inspected from 8 a.m. to 5:30 p.m., Monday through Friday, including all non-government holidays.

FOR FURTHER INFORMATION CONTACT: Kathryn Sargeant, Transportation and Market Incentives Group, Regional and State Programs Division, U.S. Environmental Protection Agency, 2565 Plymouth Road, Ann Arbor, MI 48105, (313) 668–4441.

SUPPLEMENTARY INFORMATION:

Regulated Entities

Entities potentially regulated by the conformity rule are those which adopt, approve, or fund transportation plans, programs, or projects under the Intermodal Surface Transportation Efficiency Act or Federal Transit Laws. Regulated categories and entities include:

Category	Examples of regulated entities
Local government	Local transportation and air quality agencies.
State government	State transportation and air quality agencies.
Federal government.	EPA and Department of Transportation (Federal Highway Administration and Federal Transit Administration).

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by the conformity rule. Other types of entities not listed in the table could also be regulated. To determine whether your organization is regulated by this action, you should carefully examine the applicability in § 51.394/§ 93.102 of the conformity rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

The contents of this preamble are listed in the following outline:

I. Background on Transportation Conformity Rule

Today's action proposes to amend the transportation conformity rule, ''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'' (58 FR 62188, November 24, 1993). Required under section 176(c) of the Clean Air Act, as amended in 1990, the transportation conformity rule established the criteria and procedures by which the Federal Highway Administration (FHWA), the Federal Transit Administration (FTA), and metropolitan planning organizations (MPOs) determine the conformity of federally funded or approved highway and transit plans, programs, and projects to state implementation plans (SIPs). Conformity ensures that transportation plans, programs, and projects do not produce new air quality violations, worsen existing violations, or delay timely attainment of national ambient air quality standards (NAAQS). According to the Clean Air Act, federally supported activities must conform to the implementation plan's purpose of attaining and maintaining these standards.

Since publication of the transportation conformity rule in November 1993, EPA, the Department of Transportation (DOT), and state and local air and transportation officials have had considerable experience implementing the criteria and procedures in the rule. It is that mutual

experience which leads to today's proposal, which is the third of a series of three anticipated amendments to the transportation conformity rule. In each case, the amendments were needed to clarify ambiguities, correct errors, or make the conformity process more logical and feasible. The first set of amendments was published as an interim final rule on February 8, 1995 (60 FR 7449), and was finalized on August 7, 1995 (60 FR 40098). The first set of amendments aligned the dates of conformity lapses (i.e., halting of new federally funded highway/transit projects) due to SIP failures with the application of Clean Air Act highway sanctions for certain ozone areas and all areas with disapproved SIPs with a protective finding.

The second set of amendments was proposed on August 29, 1995 (60 FR 44790), and was finalized on November 14, 1995 (60 FR 57179). The second set of amendments allowed any transportation control measure (TCM) from an approved SIP to proceed during a conformity lapse; aligned the date of conformity lapses with the date of application of Clean Air Act highway sanctions for any failure to submit or submission of an incomplete control strategy SIP; extended the grace period before which areas must determine conformity to a submitted control strategy SIP; established a grace period before which transportation plan and program conformity must be determined in newly designated nonattainment areas; and corrected the nitrogen oxides (NO_x) provisions of the transportation conformity rule consistent with the Clean Air Act and previous commitments made by EPA.

Today's proposal would further amend the conformity rule in response to several issues raised by conformity implementers and other interested parties. EPA has worked closely with these conformity stakeholders to develop this proposal. In March 1995, the National Governors' Association (NGA) and the Environmental Council of States (ECOS) hosted a meeting of state DOTs, environmental agencies, EPA, and DOT to discuss the conformity rule. At this meeting, ECOS presented nine specific proposals to change the conformity rule. EPA and DOT committed to address all nine issues. EPA requested that state workgroups prepare white papers examining four issues in greater depth: the build/no-build test, non-federal projects, rural nonattainment areas, and adding non-exempt projects to the transportation plan and transportation improvement program (TIP) without full regional analysis. The remaining five issues are being addressed administratively.

In April 1995, EPA hosted in Washington, DC a conformity stakeholder meeting of state DOTs, state environmental agencies, MPOs, environmentalists, industry groups, and other public interest groups. EPA substantially shaped the meeting's agenda around NGA's four white papers in order to provide groundwork for stakeholder discussion on these issues. On June 30, 1995, EPA distributed to conformity stakeholders draft regulatory language addressing the issues discussed at the April meeting. EPA received written comments and followed up with a series of four conference calls in July 1995 to solicit additional reaction to the June draft language. The draft language and comments are available in the public docket.

On September 1, 1995, EPA distributed a letter to conformity stakeholders indicating what EPA and DOT intended to propose regarding key conformity issues. Today's proposal is based substantially on the approach described in the September letter.

II. Applicability of the Budget Test and Emission Reduction Tests

A. Description of Proposal

The proposal would change the time periods during which the budget test and the ''emission reduction tests,'' commonly known as the ''build/no-build test,'' are required. The proposal would eliminate the requirements for the emission reduction tests once a control strategy SIP or maintenance plan has been submitted to EPA and EPA has had 45 days to review the adequacy of the SIP submission and its motor vehicle emissions budget(s). The budget test would replace the emission reduction tests 45 days after the control strategy SIP or maintenance plan was submitted to EPA (provided EPA has not found the submission inadequate), or earlier if EPA has found the submission adequate.

Under the existing transportation conformity rule, both the emission reduction tests and the budget test are required until EPA's final approval of the control strategy SIP (or maintenance plan, where control strategy SIPs are not required). In addition, under the existing rule EPA has a review period of 90 days before the motor vehicle emissions budget in a newly submitted SIP may replace a previously submitted motor vehicle emissions budget.

The proposal would streamline the conformity process by eliminating the existing transportation conformity rule's reliance on the classification system of ''Phase II interim period,'' ''transitional period,'' ''control strategy period,'' and ''maintenance period'' to determine whether the budget test and/or emission reduction tests apply.

1. Applicability of Nitrogen Oxides (NO_X) Emission Reduction Tests and Budget Tests in Ozone Areas

Under the proposal, the budget test would replace the emission reduction tests only for those pollutants for which the submitted SIP establishes a motor vehicle emissions budget. For example, 15% SIPs for ozone areas are only required to address volatile organic compounds (VOC), and as a result, most will not address NO_X or establish a NO_X emissions budget. In these areas, the VOC emission reduction tests (''build/no-build'' and less-than-1990 tests) would no longer be required, but the NO_X emission reduction tests would continue to be required until a NO_X budget is established in a submitted SIP (unless the area had received a NO_X waiver). In ozone nonattainment areas, Phase II attainment SIPs will establish NO_X motor vehicle emissions budgets.

A submitted 15% or Phase I attainment SIP would be considered to establish a NO_X motor vehicle emissions budget if the submitted SIP contains an explicit NO_X budget that is intended to act as a ceiling on future NO_X emissions and if the NO_X budget represents a net reduction from 1990 NO_X emissions levels. A submitted SIP that achieves 15% or reasonable further progress reductions by substituting some NO_X reductions for the required VOC reductions would establish a NO_X motor vehicle emissions budget.

2. EPA 45-Day Review Period

This proposal would allow conformity to be determined based on consistency with a submitted SIP's motor vehicle emissions budget(s), once the submitted SIP had been reviewed by EPA. (Of course, the submitted SIP cannot override the motor vehicle emissions budgets in an approved SIP for the years addressed by the approved SIP. See Section III.A.1.) The submitted SIP budget(s) would be used for conformity purposes beginning 45 days after the SIP's submission to EPA, provided EPA had not found the SIP and its budget(s) inadequate. The submitted SIP budget(s) would be used for determining conformity before EPA's 45-day review period expires if EPA finds the SIP and its budget(s) adequate before expiration of such 45-day period.

If EPA finds the submitted SIP and its budget(s) to be inadequate, they could not be used for conformity purposes, and conformity would have to be

determined using the previously established SIP budget(s), or the emission reduction tests, if there are no previously established SIP budgets. If EPA finds the submitted SIP and its budget(s) to be inadequate after EPA's 45-day review period and after conformity had already been determined using the submitted SIP, the conformity determination would still be valid. However, that submitted SIP and budget(s) could not be used for future conformity determinations. Projects would still be considered to come from a conforming plan and TIP if they were included in the transportation plan and TIP that were found to conform to a budget that was later declared inadequate.

In order for EPA to consider a submitted SIP's motor vehicle emissions budget(s) adequate for transportation conformity purposes, the submitted SIP must have been endorsed by the Governor (or his or her designee) and have been subject to a public hearing. The emissions budget(s) would have to be clearly identified and precisely quantified. Each emissions budget would have to be consistent with reasonable further progress, attainment, or maintenance, based upon a consideration of all emissions sources. The emissions budget(s) would have to be consistent with the area's emissions inventory and modeling assumptions for all sources and show a clear relationship between the control measures, the emissions reductions, and the resulting budgets. Each revision to a previously submitted SIP would have to identify the impacts on point, area, and mobile source emissions, as well as changes to any established safety margins. Changes to previously submitted budgets and the reasons for the changes would have to be explained and documented, including the basis for any changes related to emission factors or estimates of vehicle miles traveled (VMT), and what those changes imply for control strategies. If the revised emissions budget requires additional emission control strategies to demonstrate attainment or maintenance, such new strategies would have to be specified in the SIP submission. The SIP submission would have to contain a quantification of the emissions impacts of such new strategies and, at a minimum, commitments by appropriate agencies to a schedule for adoption and implementation, and the draft regulations or other relevant documents. Consultation among federal, state, and local agencies would have to occur and full documentation and justifications would have to be provided to EPA before the SIP is submitted. Any EPA concerns would have to be addressed before submission if the SIP and its budget(s) are to be found adequate for conformity purposes. If a SIP submission does not satisfy these conditions, EPA may find it inadequate for conformity purposes.

EPA's review of the adequacy of a SIP submission for transportation conformity purposes is separate from EPA's completeness review. EPA may find a SIP incomplete after 45 days or after finding the SIP submission adequate for transportation conformity purposes. An incomplete SIP may still have appropriate motor vehicle emissions budgets for use in the conformity process, as recognized by EPA's use of ''protective findings'' under the November 1993 transportation conformity rule. If the SIP submission is both incomplete and inadequate for transportation conformity purposes, EPA would have to declare the submission inadequate for conformity purposes in addition to finding it incomplete.

3. Areas That Are Not Required to Submit Control Strategy SIPs

Background. Under the existing transportation conformity rule, areas that are not required to submit control strategy SIPs have two options for demonstrating conformity. The first option is to satisfy the ''build/no-build'' and less-than-1990 emission reduction tests; the second is to submit a SIP that demonstrates attainment and use the budget test to determine conformity. In the latter option, such an area would be required under the existing rule to satisfy both of the emission reduction tests until the SIP is approved by EPA.

Areas affected by proposal. Marginal and below ozone nonattainment areas, not classified carbon monoxide (CO) nonattainment areas, and moderate CO nonattainment areas with a design value of 12.7 ppm or less are not required by the Clean Air Act to submit control strategy SIPs. These classifications are listed in §§ 51.464 and 93.136 of the existing transportation conformity rule.

In addition, some moderate and above ozone nonattainment areas that are meeting the ozone NAAQS are not required to submit control strategy SIPs (see May 10, 1995, memorandum from John S. Seitz, Director of the Office of Air Quality Planning and Standards, to Regional Air Division Directors, entitled ''Reasonable Further Progress, Attainment Demonstration, and Related Requirements for Ozone Nonattainment Areas Meeting the Ozone National Ambient Air Quality Standard'').

Through today's action, EPA is proposing alternatives for demonstrating conformity for particular pollutants if areas are not required to submit control strategy SIPs for that pollutant. The first alternative is currently allowed under the existing transportation conformity rule and would continue to be available under this proposal with some additional flexibilities. The second and third options would provide new alternatives to these areas for demonstrating conformity. EPA would require these areas to satisfy only one of the alternatives described below in order to demonstrate conformity.

Create a budget through the SIP process and use the budget test. As stated above, the existing transportation conformity rule and this proposal would allow these areas to submit a SIP that establishes a motor vehicle emissions budget consistent with attainment or maintenance. These areas would then be required to satisfy the budget test for each emissions budget. However, unlike the existing rule, this proposal would allow the SIP budget to be used after the SIP has been submitted to EPA and before EPA approval. The emission reduction tests would not be required once a SIP is submitted and EPA's 45-day review period has occurred (as described above).

Default budget for clean data areas. This proposal would provide another alternative for demonstrating conformity in areas that are not required to submit control strategy SIPs, and have monitoring data indicating attainment of the standard (''clean data''), but have not yet submitted a maintenance plan. These clean data areas could demonstrate conformity using the budget test instead of the emission reduction tests, using as a ''motor vehicle emissions budget'' the motor vehicle emissions levels in the most recent year of clean data. The motor vehicle emissions levels in the most recent year of clean data would be determined by the state air quality agency through the interagency consultation process. This default ''budget'' would not have to be submitted as a SIP revision and would not require special public participation in addition to that otherwise required by the transportation conformity rule. If a clean data area wishes to use a budget other than emissions levels in the most recent year of clean data, the area could submit that budget through the SIP process as described above.

Emission reduction test flexibility. Today's action would allow areas that are not required to submit control strategy SIPs another alternative when demonstrating conformity. If these areas

do not have a SIP with a motor vehicle emissions budget, this proposal would allow these areas a choice of emission reduction tests. Specifically, this proposal would allow them to demonstrate conformity by either satisfying the build/no-build test or demonstrating that annual motor vehicle emissions will not be greater than 1990 levels (i.e., the ''1990 test'').

Under the existing transportation conformity rule, these areas are required to satisfy both the build/no-build and less-than-1990 emission reduction tests in the absence of a budget. For the reasons explained below, this proposal would offer CO and ozone areas not required to submit control strategy SIPs the same flexibility currently available to PM_{10} (particles with an aerodynamic diameter of less than or equal to a nominal 10 micrometers) and nitrogen dioxide (NO_2) nonattainment areas, which are required to satisfy either the build/no-build emission reduction test or ensure that annual motor vehicle emissions will not be greater than 1990 levels.

B. Rationale

1. Elimination of the Emission Reduction Tests

A broad consensus of conformity implementers and interested parties have advised EPA that the ''build/no-build test'' has limited value in demonstrating contribution to emission reductions, or serving as the primary criterion on which conformity is based. Because of the limitations of currently available modeling tools, the build/no-build test may yield only slight differences in emissions, well within the range of modeling error. The parties have indicated that when motor vehicle emissions budget(s) have been established in submitted SIPs, they provide a more relevant basis for conformity determinations.

EPA agrees with this assessment by the transportation conformity stakeholders. EPA originally created the ''build/no build test'' and less-than-1990 tests (required by §§ 51.436–51.446 of the November 1993 transportation conformity rule) in order to implement the emission reduction requirements of Clean Air Act section 176(c)(3)(A)(iii) (for ozone and CO nonattainment areas), and to ensure that transportation activities would not increase the frequency or severity of existing violations (for PM_{10} and NO_2 nonattainment areas), as required by Clean Air Act section 176(c)(1)(B)(ii). In light of the stakeholders' input, EPA now believes that consistency with the motor vehicle emissions budget(s) in a submitted control strategy SIP or maintenance plan is sufficient to satisfy these Clean Air Act requirements.

Clean Air Act section 176(c)(3)(A)(iii) requires transportation plans, TIPs, and projects in ozone and CO nonattainment areas to contribute to annual emissions reductions consistent with sections 182(b)(1) and 187(a)(7). EPA believes that consistency with the motor vehicle emissions budgets in a submitted ozone or CO attainment SIP satisfies Clean Air Act section 176(c)(3)(A)(iii), because these budgets are intended to represent the emissions reductions necessary to attain the ozone or CO standard, as required by sections 182(b)(1) and 187(a)(7). Similarly, consistency with a submitted maintenance plan's emissions budgets fulfills the requirement to contribute to emissions reductions necessary to attain the standard, because the maintenance plan's emissions budgets represent emission levels consistent with attainment.

EPA carefully considered whether the motor vehicle emissions budget(s) established by an ozone area's submitted 15% SIP or post-1996 reasonable further progress SIP are sufficient to satisfy the requirements of Clean Air Act section 176(c)(3)(a)(iii), because such budgets do not necessarily represent the full emissions reductions necessary to attain the ozone standard. However, the motor vehicle emissions budgets in these SIPs do represent VOC emission reductions from 1990 levels. As a result, EPA believes that consistency with such a VOC budget is sufficient to satisfy the requirement of Clean Air Act section 176(c)(3)(A)(iii) for contribution to necessary emissions reductions.

EPA considered not allowing a submitted 15% SIP or post-1996 reasonable further progress SIP to establish a NO_X motor vehicle emissions budget that would be used for determining conformity instead of the NO_X emission reduction tests. The Clean Air Act does not require such SIPs to address NO_X, so a NO_X emissions budget in such a SIP could be unconstrained and would not necessarily be sufficient to satisfy section 176(c)(3)(A)(iii)'s requirement to contribute to annual emissions reductions. However, if a state establishes a NO_X emissions budget that it intends to constrain future emissions and that does represent emissions reductions from 1990 levels, EPA now believes this budget would be a better basis for determining conformity than the ''build/no-build test.'' As a result, EPA is proposing that a 15% SIP or post-1996 reasonable further progress SIP (Phase I attainment SIP) that addresses NO_X would be considered to establish a NO_X emissions budget for the purposes of transportation conformity only if that budget represented net emission reductions from 1990. Whether or not a SIP establishes a NO_X motor vehicle emissions budget should be determined in consultation with the SIP agency and the EPA Region.

For PM_{10} and NO_2 nonattainment areas, the ''build/no-build test'' and the less-than-1990 test were intended to satisfy the general definition of conformity in section 176(c)(1)(B)(ii) that transportation activities not increase the frequency or severity of any existing violation. EPA believes that consistency with the motor vehicle emissions budget(s) established in the submitted attainment SIP or maintenance plan ensures that existing violations will not be worsened by transportation projects, because these budgets represent emissions levels that are consistent with attainment of the standards.

2. Adequacy of Submitted (But Not Approved) Budgets

The November 1993 transportation conformity rule requires emission reduction tests as well as budget tests until EPA approves the submitted SIP, because EPA believed it could not be certain that submitted emissions budgets are consistent with Clean Air Act requirements for reasonable further progress, attainment, and maintenance until EPA approves the SIP. In contrast, this proposal would allow the motor vehicle emissions budgets established by submitted SIPs to be the basis of conformity determinations. (Of course, the submitted SIP cannot override the motor vehicle emissions budgets in an approved SIP for the years addressed by the approved SIP. See Section III.A.1.)

EPA now believes this is appropriate because a submitted SIP is a product of a state's interagency consultation process, which encourages discussion among state and local air quality and transportation agencies, and is ultimately endorsed by the Governor (or his/her designee). During the SIP process, states also gather information and comment from environmental groups and other interested parties at public hearings. EPA believes that these processes would ensure the credibility of a submitted SIP (and its motor vehicle emissions budgets) for the purposes of transportation conformity especially where the only alternative conformity test is the emission reduction tests. Given the limitations to the usefulness of the emission reduction tests, a submitted SIP's motor vehicle

emissions budgets are likely to be at least as good a basis for making conformity determinations, even if they are not yet approved by EPA.

EPA's proposed 45-day review period for newly submitted SIPs is intended to prevent conformity from being based on motor vehicle emissions budgets that are clearly not consistent with attainment, maintenance, or reasonable further progress. If EPA was not consulted, given sufficient information, or EPA's concerns were not satisfied prior to SIP submission sufficient for EPA to determine that the motor vehicle emissions budgets are adequate for conformity purposes during this 45-day review period, EPA could declare the motor vehicle emissions budgets inadequate and prevent their use for conformity purposes. In addition, if EPA finds the motor vehicle emissions budgets inadequate even after the 45-day review period, further conformity determinations may not be based on those budgets.

EPA considered a range of review periods after which submitted motor vehicle emissions budgets could replace emission reduction tests for determining conformity. Under the November 1993 transportation conformity rule, EPA has used a 90-day review period before a newly submitted SIP budget could replace a previously submitted budget. Many conformity stakeholders suggested a 30-day review period. EPA is proposing a 45-day review period as a compromise to balance the conflicting goals of using submitted SIP budgets as quickly as possible and preventing transportation investments from being made based on budgets that are not consistent with attainment, maintenance, or reasonable further progress. If budgets are found inadequate after conformity has already been determined, future plans and TIPs would have to offset the emissions from grandfathered projects that may have been inappropriately allowed under the inadequate budgets. This disruption could be avoided by allowing EPA enough time initially to determine the adequacy of budgets and prevent the use of inadequate budgets.

Regardless of the 45-day review period, EPA cannot ultimately ensure that a submitted SIP's motor vehicle emissions budget is consistent with reasonable further progress, attainment, or maintenance—and thus adequate to fulfill the conformity requirements of Clean Air Act section 176(c)—until EPA fully approves the SIP through notice-and-comment rulemaking. As a result, the proposal provides that reliance on a submitted SIP's motor vehicle emissions budgets for determining conformity is deemed to be a statement by the MPO and DOT that they are not aware of any information that would indicate that emissions consistent with such budgets would cause or contribute to any new violation of the relevant standard(s); increase the frequency or severity of any existing violation of the relevant standard(s); or delay timely attainment of the relevant standards or any required interim emissions reductions or other milestones. (This provision clarifies that, in the absence of EPA approval of the SIP, the MPO and DOT may not base conformity determinations on submitted SIPs that they have reason to believe do not satisfy Clean Air Act requirements.)

3. Areas Not Required to Submit Control Strategy SIPs

EPA has received public comment to extend certain flexibilities to areas that are not required to submit control strategy SIPs. The existing transportation conformity rule requires these areas to either satisfy the ''build/no-build'' and less-than-1990 emission reduction tests or submit a control strategy SIP or maintenance plan and satisfy the budget test. Today's action proposes additional flexibilities for areas that are not required to submit control strategy SIPs, including marginal and below ozone nonattainment areas, not classified CO nonattainment areas, moderate CO nonattainment areas with a design value of 12.7 ppm or less, and some moderate and above ozone areas that are meeting the ozone standard. Please refer to section II.A.3. for additional background material.

Create a budget through the SIP process and use the budget test. Although the areas discussed in this section are not required by the Clean Air Act to submit control strategy SIPs, these areas could choose to submit a control strategy SIP or maintenance plan (which contains a motor vehicle emissions budget) and demonstrate conformity by using the budget test. The existing transportation conformity rule requires consistency with the SIP's motor vehicle emissions budget as stipulated in Clean Air Act section 176(c)(2)(A). This option is available both in the existing transportation conformity rule and this proposal.

Default budget for clean data areas. This proposal would allow areas with clean monitoring data but no submitted or approved budget to determine conformity using the budget test, with the motor vehicle emissions levels in the most recent year of clean data serving as the ''budget.'' In order for data to be considered ''clean,'' it must meet EPA's requirements and guidance for acceptable monitoring. EPA is also proposing this second option because many areas would prefer to determine conformity using a budget test rather than the emission reduction tests, but are nevertheless unwilling to devote resources to creating a motor vehicle emissions budget through the SIP process. The motor vehicle emissions in the most recent year with clean data is an adequate ''default budget'' that can be determined without using the formal SIP process. This level of motor vehicle emissions does not automatically demonstrate attainment, because it does not consider the levels of emissions from other sources. However, these areas are not required by the Clean Air Act to submit attainment demonstrations. Furthermore, this level of motor vehicle emissions does produce clean data. Therefore, EPA believes that requiring consistency with the level of motor vehicle emissions in the most recent year of clean data is a reasonable test, and one that is likely to be more meaningful than the emission reduction test (for the reasons discussed earlier).

Emission reduction test flexibility. This proposed alternative would allow areas that are not required to submit control strategy SIPs that do not choose the other two options in this section to satisfy either the build/no-build test or demonstrate that annual motor vehicle emissions will not be greater than 1990 levels (i.e., the ''1990 test''), provided these areas do not have an approved budget in a control strategy SIP or maintenance plan. EPA is proposing this flexibility because conformity stakeholders have indicated that, like PM_{10} and NO_2 areas, the ozone and CO classifications listed in §§ 51.464 and 93.136 of the transportation conformity rule and moderate and above ozone nonattainment areas that are affected by the May 10, 1995, EPA memorandum (see section II.A.3. for more information) are not subject to sections 182(b)(1) and 187(a)(7) of the Clean Air Act.

The existing transportation conformity rule requires that areas without motor vehicle emissions budgets must satisfy both the build/no-build and less-than-1990 emission reduction tests in order to demonstrate conformity. EPA originally created these tests in order to implement the emission reduction provisions of Clean Air Act section 176(c)(3)(A)(iii), which requires ozone and CO areas to contribute to annual emission reductions consistent with sections 182(b)(1) and 187(a)(7). However, sections 182(b)(1) and 187(a)(7) only apply to moderate and above ozone nonattainment areas and

CO nonattainment areas that are moderate greater than 12.7 ppm.

PM_{10} and NO_2 areas are similarly not required to satisfy the annual emission reduction provisions of Clean Air Act section 176(c)(3)(A)(iii). The existing transportation conformity rule and this proposal require PM_{10} and NO_2 areas to satisfy either the build/no-build or 1990 test in order to demonstrate conformity.

EPA originally required both the build/no-build and less-than-1990 tests for all ozone and CO areas in order to ensure that transportation planning does not produce new air quality violations, worsen existing violations, or delay timely attainment of the NAAQS, as required by Clean Air Act section 176(c)(1)(B). However, EPA now believes that, for these areas which were never subject to the emission reduction mandate of section 176(c)(3)(A)(iii), either the build/no-build test or the 1990 test is sufficient to satisfy the requirements of the Clean Air Act.

III. Implementation of the Budget Test

A. Which Budgets Apply?

1. Approved SIPs Versus Submitted SIPs

Years that are directly addressed by the approved SIP. Motor vehicle emissions budgets in an approved SIP (i.e., the applicable implementation plan) must always be used for demonstrating satisfaction of the budget test for those years in the timeframe of the transportation plan that are addressed by the approved SIP. That is, if the approved SIP establishes a motor vehicle emissions budget for a year in the timeframe of the transportation plan, consistency with that budget must be demonstrated for that year. A submitted SIP cannot override the motor vehicle emissions budgets in an approved SIP for the years addressed by the approved SIP.

Clean Air Act section 176(c) specifically requires conformity to approved implementation plans. The provisions of an implementation plan that EPA has approved under Clean Air Act section 110 are enforceable and cannot be changed on the basis of a submission. As a result, although some conformity implementers and interested parties requested that they be permitted to replace approved SIP budgets with submitted SIP budgets, EPA believes that this cannot be legally allowed. In addition, approved SIP budgets have been subject to full technical review and public comment and should not be replaced by budgets that have not yet been fully analyzed and reviewed.

Years that are not directly addressed by the approved SIP. However, this proposal would allow a submitted SIP's motor vehicle emissions budgets to be used instead of the approved SIP's budgets for those years not directly addressed by the approved SIP. For example, for a serious ozone nonattainment area, the approved 15% SIP's VOC budget would have to be used to demonstrate the budget test for 1996, but the submitted attainment SIP's budget would be used to demonstrate the budget test for the attainment year (1999).

Similarly, this proposal would allow a submitted maintenance plan's motor vehicle emissions budgets to be used for the years after the attainment year, instead of continuing to use the approved attainment year budget for those subsequent years. Under the existing transportation conformity rule, a submitted maintenance plan's motor vehicle emissions budget(s) may not be used for transportation conformity purposes until the maintenance plan has been approved.

EPA believes this flexibility is appropriate because any given approved SIP is only intended to address a certain period of time. In general, attainment SIPs address only the period through the attainment year, and maintenance plans address at a minimum a ten-year period. EPA believes that the Clean Air Act's reference to conformity to ''approved implementation plans'' applies to the years which the approved SIP addresses, and that this language should not prohibit using as the relevant test of conformity subsequent SIP submissions that address later years. EPA believes that the submitted maintenance plan's motor vehicle emissions budgets are more relevant to the years after the attainment year than the attainment year budget in the approved attainment SIP. Similarly, a submitted attainment SIP's budget is more relevant for the attainment year than an approved post-1996 SIP budget. EPA had previously required use of the last budget in the approved SIP for all subsequent years only because there was no other budget against which to determine conformity. Once such a budget is submitted, it provides the most relevant basis for testing conformity.

If no SIP is submitted that addresses the years after the approved SIP, the approved SIP's budget(s) would continue to apply for the future years in the timeframe of the transportation plan.

Changes to approved SIPs. This proposal would not alter the fact that proposed changes to an approved SIP cannot be used for the purposes of transportation conformity until those changes are approved. For example, if an area submits a proposed revision to a SIP with an attainment year budget to replace the approved attainment SIP, that SIP submission cannot be used until it is approved by EPA.

2. Multiple SIP Submissions

How soon can a newly submitted SIP replace a previously submitted SIP? Under this proposal, the most recent SIP submissions would replace other prior SIP submissions that have not yet been approved. If an area submits a SIP to revise motor vehicle emissions budgets in a SIP that has not yet been approved, the most recent SIP submission would be used for demonstrating the budget test beginning 45 days after submission to EPA (provided EPA has not found the submission inadequate), or earlier, if EPA has found the submission to be adequate.

Under the existing transportation conformity rule, a newly submitted SIP is not permitted to replace a complete SIP submission for 90 days. If EPA found the newly submitted SIP complete in less than 90 days, either SIP submission could be used for conformity determinations made during the first 90 days after SIP submission. This proposal would require the most recent SIP submission to be used for conformity purposes after 45 days (if it has not been found inadequate), or as soon as it has been found adequate, if this occurs in less than 45 days after submission to EPA.

EPA is proposing this change for several reasons. First, due to conformity stakeholder suggestions that submitted SIPs should be used sooner for conformity purposes, EPA is proposing to shorten the existing transportation conformity rule's 90-day grace period to 45 days. In addition, EPA is interested in streamlining the transportation conformity rule and reducing ambiguity in its implementation. There has been substantial confusion in implementation of the existing transportation conformity rule regarding which submitted SIP's budgets should be used for conformity purposes, and at which times. EPA believes that it is simpler and truer to the spirit of conformity to require the most recently submitted SIP (that has undergone 45-day EPA review) to be used for determining conformity.

EPA believes that the simplicity gained from this change outweighs any potential limitation to the flexibility of areas to choose among SIP submissions in the first few weeks after submission. In many instances, SIP submissions intended to replace previous SIP submissions were either inspired by conformity considerations or represent a more accurate basis for conformity. As

a result, most areas would not choose to use the previous SIP submission even if given the opportunity.

In addition, the protection EPA originally intended the 90-day grace period to provide is under the state's control. EPA did not originally require newly submitted SIPs to be used in the first 90 days, because EPA did not want conformity determinations that were underway at the time of the SIP submission to be disrupted. However, this protection is not necessary in the conformity rule itself, because the state controls when it submits a SIP, and the interagency consultation process gives state and local agencies an opportunity to coordinate conformity determinations and SIP submissions to avoid disruption of the conformity process. EPA believes that the ambiguity regarding which SIP submission is used for conformity is more problematic than the remote possibility that a SIP submission would interfere with a conformity determination that was underway.

When should different submitted SIPs be used? When a series of control strategy SIPs have been submitted to fulfill different Clean Air Act requirements for a particular pollutant, the budget test would be demonstrated using each relevant submitted SIP that is adequate for conformity purposes. For example, the proposal would require the submitted post-1996 reasonable further progress SIP's motor vehicle emissions budgets to be used for demonstrating the budget test for milestone years, and would require the submitted attainment demonstration's budget(s) to be used for demonstrating the budget test for the attainment year. SIP budget(s) that address the latest future year would apply for all subsequent years in the timeframe of the transportation plan.

B. Control Strategy SIPs and Maintenance Plans That Do Not Establish Motor Vehicle Emissions Budgets

This proposal would clarify that the emissions budget test must be satisfied only for those pollutants and pollutant precursors for which a motor vehicle emissions budget is established. Normally, a control strategy SIP or maintenance plan would by its nature include a motor vehicle emissions budget for each pollutant and pollutant precursor for which the area was designated nonattainment. These budgets are created by the control strategy SIP or maintenance plan even if they are not clearly identified, and failure to clearly identify a motor vehicle emissions budget does not relieve the requirement to satisfy the budget test. However, as explained further below, there are some cases in which a SIP could specifically provide that no motor vehicle emissions budget was established for transportation conformity purposes, and in such cases, the budget test would not have to be satisfied for that pollutant or precursor.

Certain nonclassifiable ozone areas have the option to submit a ''limited maintenance plan,'' which would not establish motor vehicle emissions budgets. According to the November 16, 1994, memorandum from Sally Shaver, Director of EPA's Air Quality Strategies and Standards Division, to EPA Regional Air Division Directors, entitled ''Limited Maintenance Plan Option for Nonclassifiable Ozone Nonattainment Areas,'' nonclassifiable ozone areas whose design values are at or below 0.106 ppm (85% of exceedance levels of the ozone standard) at the time of redesignation may choose to submit a less rigorous maintenance plan than required for other areas. This ''limited maintenance plan'' would not be required to project emissions over the maintenance period, and as a result, no motor vehicle emissions budget would be established. There are similar policies for CO and PM_{10} areas that may also result in no motor vehicle emissions budgets being established.

In other cases, the control strategy SIP or maintenance plan could explicitly demonstrate that motor vehicle emissions are not a significant contributor to the nonattainment problem, and the SIP could explicitly state that it is not establishing a motor vehicle emissions budget for transportation conformity purposes. This could occur, for example, in CO and PM_{10} areas that are dominated by stationary sources. In order for EPA to approve or find adequate for conformity purposes a SIP that makes a claim of insignificance, the SIP would have to demonstrate that it would be unreasonable to expect that such an area would experience enough motor vehicle emissions growth for a violation to occur. Such a demonstration would have to be based on a number of factors, including the percentage of the inventory comprised by motor vehicle-related emissions currently and in the future, how close the monitoring data is to the standard, the absence of SIP motor vehicle control measures, historical trends in the growth of motor vehicle emissions and VMT, and projections of motor vehicle emissions and VMT.

If EPA's 45-day review period expires without EPA finding the SIP either adequate or inadequate for conformity purposes, the submitted SIP's claim of insignificance may be used to justify not demonstrating satisfaction of the budget test (unless or until EPA finds the SIP inadequate).

When a control strategy SIP or maintenance plan does not establish motor vehicle emissions budgets, no regional emissions tests would be required to be satisfied. That is, neither the emissions budget test nor the emission reduction tests would be required to be satisfied.

C. For Which Years Would the Budget Test Be Demonstrated?

This proposal would clarify (without changing the substance of) the existing transportation conformity rule's requirements regarding the years for which the budget test must be demonstrated. The proposal would explicitly require the budget test to be demonstrated for each year for which the SIP establishes a motor vehicle emissions budget. For example, the attainment SIP generally establishes a budget for the attainment year, and the 15% SIP establishes a VOC budget for 1996. SIPs may explicitly include motor vehicle emissions budgets for other years not specifically required to be addressed by the Clean Air Act. For example, an attainment SIP or a maintenance plan may address more years than required by the Clean Air Act and explicitly include motor vehicle emissions budgets for those years. In such cases, the budget test would have to be demonstrated for the years for which a budget was specifically established.

The budget test must be demonstrated for the last year of the maintenance plan and any other years for which the maintenance plan establishes motor vehicle emissions budgets. An area may choose to explicitly establish motor vehicle emissions budgets for years in the timeframe of the maintenance plan other than the last year. In such cases, compliance with the budget test would have to be demonstrated for those years. Some maintenance plans may include specific motor vehicle emissions projections for some or all years in the timeframe of the maintenance plan, without intending that such projections operate as limitations on emissions. The budget test would not be required to be demonstrated for these years unless it was the intent of the maintenance plan to establish a budget for these years. Such issues should be addressed when developing the control strategy SIP or maintenance plan. For control strategy SIPs and maintenance plans that have already been submitted, the state's intent regarding the use of motor vehicle emissions budgets may be clarified

through the interagency consultation process.

In addition to the years for which the SIP establishes a motor vehicle emissions budget, the budget test must be demonstrated for the last year of the transportation plan's forecast period. If there are more than ten years between the years for which the SIP specifically establishes motor vehicle emissions budgets, the budget test must also be demonstrated for some intermediate years so that the budget test is demonstrated at ten-year (or shorter) intervals.

Regional emissions analysis. Satisfaction of the budget test requires comparison of the motor vehicle emissions budget with regional emissions predicted for a given year. A regional emissions analysis must be performed for each pollutant and precursor for the last year of the transportation plan's forecast period and the attainment year (if it is in the timeframe of the transportation plan). For the other years for which the budget test is required to be demonstrated, the estimate of regional emissions does not necessarily need to be based on a regional emissions analysis performed for that specific year; the estimate of regional emissions may be based on an interpolation between the years for which the regional emissions analysis was performed. However, the years for which the regional emissions analysis is performed must be no more than ten years apart.

D. Maintenance Plans

The proposal would require that if the maintenance plan does not establish motor vehicle emissions budgets for any years other than the last year of the maintenance plan, the demonstration of consistency with the motor vehicle emissions budget(s) must be accompanied by a qualitative finding that there are no factors which would cause or contribute to a new violation or exacerbate an existing violation in the years before the last year of the maintenance plan.

Because the maintenance plan is required by the Clean Air Act to demonstrate maintenance of the standards over a 10-year period, general consistency between the latest planning assumptions and the maintenance plan's assumptions and projections is a basis for finding that there will not be new or worsened violations during that period. Each maintenance plan will have different assumptions and projections, so the specific basis for an area's qualitative finding will need to be determined through the interagency consultation process. The qualitative finding would be contained in the documentation that demonstrates that the budget test has been satisfied.

EPA believes a qualitative finding is necessary if the budget only addresses the last year of the maintenance plan, because the budget test alone is not sufficient to determine, as required by the Clean Air Act, that the transportation action will not cause a new violation. The emissions impacts in the initial ten years of the maintenance plan must be considered in some manner in order to determine conformity.

EPA believes that requiring a qualitative finding is preferable to requiring maintenance plans to establish motor vehicle emissions budgets for specific years. Although maintenance plans contain projections for intermediate years that could be used as motor vehicle emissions budgets, EPA believes that the years for which budgets are established should be decided by the state. EPA is willing to allow states to establish budgets only for the last year of the maintenance plan, provided conformity determinations are accompanied by a qualitative finding addressing the intermediate years. Alternatively, states could choose to establish motor vehicle emissions budgets for intermediate years in the maintenance plan, which would then be used to determine conformity.

IV. Non-federal Projects

A. Description of Proposal

This proposal would allow regionally significant transportation projects that are funded or approved by a recipient of federal funds designated under title 23 U.S.C. or the Federal Transit Laws (49 U.S.C. Chapter 53) which do not rely at all on any FHWA/FTA funding or approvals (i.e., ''non-federal projects'') to be adopted or approved during a transportation plan/TIP conformity lapse, provided the project was included in the regional emissions analysis supporting the most recent transportation plan and TIP conformity determination. Also, the project's design concept and scope could not have changed significantly from that included in the previous emissions analysis.

The existing transportation conformity rule requires a currently conforming transportation plan and TIP to be in place at the time a recipient of federal funds adopts or approves a regionally significant non-federal project. As a result, no regionally significant non-federal projects can be adopted or approved during a transportation plan/TIP conformity lapse.

Under both this proposal and the existing transportation conformity rule, adoption or approval of non-federal projects that are not regionally significant is not subject to any transportation conformity requirements. In addition, under both this proposal and the existing transportation conformity rule, there is a provision for regionally significant non-federal projects to be added to the existing transportation plan and TIP's regional emissions analysis, if the transportation plan and TIP are currently conforming. That is, if a regionally significant non-federal project has not previously been included in the regional emissions analysis supporting the transportation plan and TIP conformity determinations, another regional emissions analysis could be performed including the transportation plan and TIP projects and the additional regionally significant non-federal project. If this analysis demonstrates that the currently conforming transportation plan and TIP would still conform if the non-federal project were implemented, the non-federal project could be adopted or approved.

Some commenters have suggested that if certain non-federal projects are to be permitted to be adopted or approved during a transportation conformity lapse as EPA is currently proposing, each such project should be approved by the Governor. This provision would provide greater assurance that the emissions consequences of proceeding with projects during a conformity lapse are consciously accepted. However, EPA is not proposing this limitation at this time because such a limitation is not explicitly required by the Clean Air Act, and it is not clear which state and local government officials should have the authority to adopt or approve non-federal projects during a conformity lapse. EPA is interested in receiving comment on this subject.

B. Rationale

EPA is proposing to allow some regionally significant non-federal projects to be adopted or approved during a conformity lapse in response to comments from conformity implementers. These comments stated that state and local governments should have the discretion to accept the emissions consequences of projects that are under their control to fund and approve, even when there was not a conforming transportation plan and TIP. Future transportation plans and TIPs are required to consider the emissions from regionally significant non-federal

projects, so any necessary offsets would ultimately be achieved.

EPA believes this proposal is consistent with the requirements of Clean Air Act section 176(c). Section 176(c)(2)(C) requires transportation projects to ''come from a conforming plan and TIP.'' EPA has interpreted this in the existing conformity rule to mean that a conforming transportation plan and TIP must be in place at the time of project adoption or approval, and that the project must be included in the transportation plan and TIP (or regional emissions analysis supporting the conformity determination for the transportation plan and TIP). EPA now believes that because non-federal projects are not federally funded or approved, it is not necessary for a conforming transportation plan and TIP to be in place at the time of project adoption or approval. The transportation plan and TIP are not relevant as a funding mechanism for non-federal projects. The crucial requirement for non-federal projects is previous inclusion in the regional emissions analysis supporting a conforming transportation plan and TIP. That is, the area had previously considered the emissions of the non-federal project and concluded that they could be accommodated in the planned transportation network without adversely affecting air quality.

The option provided in section 176(c)(2)(D) for new projects that were not previously included in a transportation plan/TIP or supporting regional emissions analysis to demonstrate conformity cannot apply during a transportation plan/TIP conformity lapse, because it requires a demonstration that ''conforming transportation plans and TIPs'' would still conform when the emissions of the new project are considered. Without a conforming transportation plan and TIP in place, this cannot be demonstrated.

This proposal would require that a regionally significant non-federal project be included in the regional emissions analysis supporting the most recent transportation plan and TIP conformity determinations, rather than any previous conformity determination. This is because each regional emissions analysis must include all regionally significant transportation projects in the timeframe of the transportation plan. Therefore, even if there is no current activity on a particular non-federal project at the time of the most recent transportation plan/TIP conformity determination, it still will have been included in the regional emissions analysis. If a non-federal project were included in the regional emissions analysis from an older transportation plan/TIP conformity determination and not from the most recent, this would indicate that the project is no longer expected to occur in the timeframe of the transportation plan and TIP. As a result, it could no longer be assumed that implementation of the project could be accommodated with no adverse air quality impact.

EPA has received comment opposing the adoption or approval of non-federal projects during a transportation conformity lapse. Commenters believe that building new projects during a time when a conforming transportation plan and TIP has not been developed would only increase the difficulty of plan/TIP development in the future. However, as described above, EPA believes that this proposal is consistent with the Clean Air Act. In addition, the limitation that regionally significant non-federal projects must have been part of the most recent prior regional emissions analysis supporting the most recent conforming transportation plan and TIP ensures that the emissions consequences of the projects have been considered, and the decision to proceed with such projects during a conformity lapse could be made with full knowledge of the possible emissions implications. These non-federal projects would then have been considered as part of the transportation planning process, and because these projects are not able to avoid the scrutiny of the metropolitan planning process during a conformity lapse, there would not be unequal requirements that would provide an incentive to shift the funding of projects from federal to non-federal sources.

EPA has also received comment that any non-federal project, whether or not it has previously been included in a regional emissions analysis supporting a transportation plan/TIP conformity determination, should be allowed to proceed during a transportation plan/TIP conformity lapse. However, EPA continues to believe, as described in the preamble to the November 24, 1993, transportation conformity rule, that Clean Air Act section 176(c)(2)(C)'s requirements for ''transportation projects'' refer to any highway or transit projects, not just those that are federally funded or approved. Thus, EPA believes that regionally significant non-federal projects must have been considered in a previously conforming emissions analysis in order to be adopted or approved.

V. Rural Nonattainment and Maintenance Areas

A. Description of Proposal

Isolated rural nonattainment and maintenance areas with submitted or approved control strategy SIPs or maintenance plans would be allowed, under this proposal, to choose among several tests for demonstrating conformity for years after the time period addressed by the SIP (e.g., years after the attainment year or the last year of the maintenance plan).

These areas could either (1) demonstrate consistency with the most recent motor vehicle emissions budget(s), as normally required; (2) satisfy the emission reduction tests (''build/no-build test'' and/or less-than-1990 test, depending upon classification); or (3) demonstrate through air quality dispersion modeling that the FHWA/FTA project, in combination with all other regionally significant projects expected in the area in the timeframe of the statewide transportation plan, satisfies the general definition of conformity in Clean Air Act section 176(c)(1) (i.e., the project will not cause or contribute to any new violations; increase the frequency or severity of any existing violation; or delay timely attainment or required interim emission reductions).

The choice among these conformity tests and the methodology for air quality dispersion modeling would be determined through the interagency consultation process and reflect the consensus of the state and local air and transportation agencies and the project sponsor. EPA and DOT would also have to be consulted through the usual interagency consultation process.

Isolated rural areas would be defined as nonattainment and maintenance areas (or portions thereof) that do not have a metropolitan transportation plan or TIP and whose projects are not part of the emissions analysis of any MPO's transportation plan or TIP. This would not include ''donut'' areas that are outside the metropolitan planning boundary and inside the nonattainment/maintenance area boundary, because these projects must be considered in the context of the MPO's transportation plan and TIP, even if the MPO does not specifically include them in the transportation plan/TIP or the MPO's own regional emissions analysis.

Because air quality dispersion modeling for ozone is often complex and resource-intensive, EPA does not expect that this particular option will be viable for isolated rural ozone nonattainment and maintenance areas. However, this is a more realistic option

for such CO and PM_{10} nonattainment and maintenance areas and is being considered at the request of several commenters.

This proposal differs from the existing transportation conformity rule by offering several options for demonstrating conformity in years after the time period addressed by the SIP. The existing transportation conformity rule would require the motor vehicle emissions budget established for the most recent prior year to be used for the purpose of demonstrating transportation conformity for all subsequent years in the timeframe of the transportation plan.

B. Rationale

In response to comments from those implementing conformity as well as from other interested parties, EPA is proposing flexibility for isolated rural nonattainment and maintenance areas. The general issue of conformity for years outside the timeframe of the SIP is explained below in section VIII., ''Mismatch in SIP/Transportation Plan Timeframe.'' EPA is here proposing flexibility for isolated rural nonattainment and maintenance areas, and not for other areas, because isolated rural areas face unique challenges in addressing this issue.

Isolated rural areas generally do not have a metropolitan transportation planning process that could serve as a forum for identifying and addressing long-term growth issues in years not addressed by the SIP. In addition, regionally significant, federally funded or approved projects usually occur infrequently in isolated rural areas. Conformity demonstrations for such areas as required by the existing conformity rule would place the burden of long-term planning on a few or even a single transportation project.

EPA believes this places an inappropriately large burden on sponsors of such federally funded or approved transportation projects. Although conformity is intended to assure long-term planning, EPA believes it is appropriate to impose conformity requirements involving less rigorous long-term planning in areas where comprehensive planning processes including land use and other issues do not otherwise exist or are not otherwise required.

Some conformity implementers suggested that the flexibility for isolated rural areas should apply for ''donut'' areas that are outside MPO planning boundaries but within urbanized nonattainment areas. EPA does not believe this is appropriate because donut areas do not face the same challenges as truly isolated rural areas. Conformity determinations by the MPO must consider motor vehicle emissions from all projects in the nonattainment or maintenance area, including emissions from projects in the donut area. Thus, there is a planning process that in some manner addresses the donut area. The Intermodal Surface Transportation Efficiency Act (ISTEA) envisioned that in most cases, the MPO planning boundary would be consistent with the nonattainment area boundary. To the extent that conformity poses a burden on the donut area because the area does not have long-term planning capabilities, arrangements could be made with the adjacent MPO.

EPA believes that providing some flexibility for the years not addressed by the SIP is consistent with the Clean Air Act (see section VIII. below). The Clean Air Act requirement for consistency with the SIP's emissions reduction goals could be construed to apply only for the years that an individual SIP revision addresses. The time period later than that addressed by SIPs is in some ways analogous to the time period before SIPs are developed, and as such the emission reduction tests (''build/no-build'' and less-than-1990 tests) may also be appropriate for the time period after that addressed by SIPs. Air dispersion modeling that directly demonstrates satisfaction of the general definition of conformity is clearly also consistent with Clean Air Act section 176(c).

EPA is proposing that the choice of conformity tests for isolated rural areas for years not addressed by a SIP should be made with the agreement of relevant state and local agencies. EPA believes this is necessary because MPOs are authorized by the Clean Air Act to determine conformity and there are no MPOs in isolated rural areas; thus, there is no single state or local agency with authority for determining conformity. Various state and local agencies may have differing perspectives on the practicality and benefits of the different conformity tests. As a result, EPA believes the method for demonstrating conformity should be a consensual decision by all relevant state and local agencies, so that all relevant actors in an area can weigh the advantages and disadvantages of each method of demonstrating conformity.

EPA also believes that the methodology for performing air quality dispersion modeling should have the agreement of all relevant state and local agencies. The air agency traditionally has responsibility for performing air quality dispersion modeling, but some other agency may take responsibility for such modeling with respect to a given project for the purposes of transportation conformity in rural areas. Therefore, EPA believes that all agencies should agree on the methodology to be used.

EPA considered requiring EPA approval of the modeling methodology used in isolated rural areas, because air quality dispersion modeling used in SIPs is traditionally governed by EPA guidance and regulations. If air quality dispersion modeling that is used to demonstrate conformity with the purpose of the SIP is based on different assumptions than the SIP itself used, the determination of conformity could be suspect. However, commenters convincingly argued that requiring concurrence of the state air agency accomplishes the goal of assuring consistency with the SIP's air quality dispersion modeling methodology, and that further concurrence by EPA would be an unnecessary administrative burden for isolated rural areas.

The option to demonstrate conformity using air quality dispersion modeling in certain cases was specifically requested by conformity implementers. Because EPA believes using air quality dispersion modeling for conformity demonstrations for years not addressed by SIPs would be consistent with Clean Air Act section 176(c) requirements (see above), EPA is proposing this additional flexibility for all isolated rural areas. Areas for which air quality dispersion modeling is too resource-intensive may of course choose one of the other methods of demonstrating conformity.

EPA considered allowing isolated rural areas to include non-federal projects in either the ''build'' or ''no-build'' case when performing the ''build/no-build test,'' at the discretion of state and local air and transportation agencies. Conformity implementers and interested parties had noted that because regionally significant federally funded or approved transportation projects occur relatively infrequently in isolated rural areas, considering (and potentially offsetting) the emissions impacts of non-federal projects posed an unfair burden on the few federal projects. However, EPA believes that despite the differing practical considerations for urban and rural areas, there is no legally defensible distinction between what constitutes a contribution to emissions reductions in rural vs. urban areas. Because EPA believes that the ''build/no-build'' test demonstrates contribution to emissions reductions only when new non-federal projects are included in the ''build'' case, EPA is not proposing to alter the build/no-build test's treatment of non-federal projects in rural areas.

Some conformity implementers suggested to EPA that conformity in isolated rural areas be demonstrated using a project-level ''build/no-build test.'' Although it is true that isolated rural areas do not have local transportation plans and TIPs as referred to in Clean Air Act section 176(c)(2) (C) and (D), EPA believes that it is the intent of the Clean Air Act for the regional emissions impacts of transportation projects to be considered in the context of other transportation projects in the nonattainment or maintenance area. Furthermore, EPA questions whether it is possible for areas concerned with regional pollutants to determine whether a project will cause or contribute to new violations or exacerbate existing violations without considering other transportation projects planned for the area. Therefore, EPA is not proposing the option to use a project-level analysis for the build/no-build test in rural areas.

VI. Modeling Requirements

A. Network Modeling Requirements

1. Deadline for Use of Network Models

This proposal would require that serious CO and serious, severe, and extreme ozone areas use network models to support conformity determinations by January 1, 1997. This requirement would apply only to those metropolitan planning areas with an urbanized area population over 200,000. Areas that are already using accepted network modeling practices would be required to continue using them for conformity analyses performed before January 1, 1997. Areas would continue to be required to have a consultation process to select regional models and assumptions.

The existing transportation conformity rule required that all serious CO and serious and above ozone areas use network modeling for conformity analyses by January 1, 1995. This proposal extends the deadline to January 1, 1997. EPA received several comments related to the ambitious nature of the 1995 deadline, and it has become increasingly apparent that the original deadline is creating difficulties for several areas that have been unable to comply by that date. Based on comments received, EPA has determined that January 1, 1997, would be a reasonable extension of the deadline. EPA believes that this deadline would allow areas experiencing difficulties to improve and implement their network models, while requiring that areas currently using network modeling continue to do so prior to that date.

In serious CO areas and serious and above ozone areas, conformity determinations may be made after January 1, 1997, based on regional emissions analysis that does not use network modeling only if that regional emissions analysis was performed in support of the proposed conformity determination before January 1, 1997. It is not necessary for the MPO or DOT to complete its determination process before January 1, 1997, if the regional emissions analysis supporting the determination was completed before January 1, 1997. It is also permissible for a proposed transportation plan or TIP, and/or the regional emissions analysis associated with it, to be modified to a reasonable degree after January 1, 1997, as a result of the public participation process.

This interpretation of the deadline for modeling improvements is described in a December 30, 1994, letter from Philip A. Lorang, EPA's Director of Emission Planning and Strategies Division, to Cynthia Burbank, FHWA's Environmental Analysis Division Chief, and Samuel Zimmerman, FTA's Director of the Office of Planning.

2. Areas Subject to Deadline for Use of Network Models

This proposal would limit the requirement to use network modeling to metropolitan planning areas with an urbanized area population over 200,000, whereas the existing rule's requirements apply to all nonattainment areas in these classifications, regardless of population or urbanization. The proposed limitation results from a general concern that the modeling requirements are overly burdensome for small and rural areas within serious ozone nonattainment areas, such as Martha's Vineyard Island, Massachusetts. EPA considered but is not proposing a three-tiered scenario in which an area's modeling requirements would have varying specificity based on its population and whether it was urban or rural. Commenters believed that such a detailed proposal would unnecessarily increase the rule's complexity. As a result, EPA decided to specify requirements only for those serious, severe and extreme areas with an urbanized area population over 200,000. The 200,000 population level was chosen because it is also the population level used to delineate transportation management areas (TMAs). EPA believes that these limitations would ensure that smaller areas no longer are required to use unnecessarily stringent network modeling procedures and methods.

EPA received a comment that suggested a specific, two-part process for network model improvements in serious CO and serious and above ozone nonattainment areas. The first part recommended an expanded, tiered set of deadlines based on nonattainment status, population, and growth rate, with added flexibility through a waiver provision if mobile sources were clearly not a factor in an area's nonattainment problem. The second part suggested that the MPO prepare a strategic plan for the area's modeling improvements. The MPO would also be responsible for encouraging public participation in this process and making available for public comment the documentation of conformity determinations and information relevant to improving the regional analysis systems.

EPA decided not to propose this approach for several reasons. First, the tiered deadline concept would expand the modeling requirements to areas not currently affected under the existing rule. EPA believes that these modeling requirements are not necessary in all nonattainment areas and that this concept would further increase the rule's complexity. Second, although EPA agrees with the importance of strategic planning in modeling improvements, the Agency believes that the existing interagency consultation process provides areas with the necessary flexibility in planning for modeling improvements.

3. Content of Modeling Requirements: Request for Comment

In today's proposal, EPA is proposing regulatory text that would amend the requirements addressing the characteristics of network models. Under § 51.452(b)(93.130(b)) of the November 1993 conformity rule, network-based models used in serious and above CO and ozone areas for conformity analyses are required to possess eleven specific modeling attributes. EPA originally developed these eleven attributes in consultation with conformity stakeholders and with the understanding that they represented modeling procedures that are currently available and in practice. EPA continues to believe that these modeling attributes would encourage improved network-based modeling.

However, stakeholders have since suggested that the modeling requirements in the existing rule create too much complexity and rigidity in the conformity rule. As a result, EPA is proposing regulatory text today that would remove these eleven modeling attributes from the rule and replace them with modeling guidance

periodically issued by EPA and DOT. Today's proposal is described below as Option 1.

Since several stakeholders have expressed concern over the primary option EPA is proposing today (Option 1), two alternative options are also described below. All three of the options described below would apply to nonattainment areas with urbanized population over 200,000, as described above. EPA requests comment on all of these options, and depending on the public comment received, EPA may finalize one of these alternative approaches, instead of the primary option EPA is proposing today.

EPA believes that the conformity rule would still be consistent with the letter and intent of Clean Air Act section 176(c) if any of the proposed changes to the modeling requirements are adopted. Since the statute does not specifically address modeling requirements, EPA believes that so long as the modeling requirements continue to ensure that conformity determinations are based on sound quantitative analysis, EPA has the discretion to determine appropriate methods for implementing those requirements.

Option 1: Address Network Modeling Attributes in Guidance. EPA proposes today that the specific attributes of network models that are required under the existing transportation conformity rule be removed from the regulatory text and instead be addressed in guidance documentation. EPA believes that this proposal will simplify the conformity rule and ensure that areas will be able to choose the modeling procedures that best match their current modeling and air quality planning needs, resource constraints, and technical expertise capability.

In order to ensure that appropriate modeling tools are employed, EPA and DOT will periodically issue modeling guidance comprised of technical documentation and other references describing available modeling procedures. This guidance is likely to be a combination of existing and new documents or references to technical information taken from a variety of sources. Many of the detailed attributes required under the existing transportation conformity rule will be referenced in this guidance. By issuing technical guidance documents on a regular basis, EPA and DOT will be able to communicate new modeling practices and encourage continuous improvement over time.

EPA is aware that removing the regulatory requirements governing network model performance may be perceived by some to be an endorsement of less rigorous modeling practices. However, EPA and DOT remain committed to developing and encouraging improved transportation models and to ensuring that areas continue to employ good modeling practices. Today's proposal is intended as a streamlining measure, not a relaxation of standards for acceptable modeling. EPA believes that guidance regarding available modeling techniques will facilitate model improvement at least as well as including specific modeling requirements in the conformity rule, while responding to local needs for flexibility. The agencies believe that agreement regarding appropriate modeling techniques and improvements for each area should be an important focus of the interagency consultation process as currently required by § 51.402 (c)(1)(i) and (c)(6) and § 93.105 (c)(1)(i) and (c)(6).

Option 2: Retain Network Model Performance Requirements in Existing Conformity Rule. This option would retain all of the eleven characteristics of network models that are required in the November 1993 conformity rule. For example, network models in these areas would continue to be required to meet performance-based standards such as capacity-sensitive assignment and reasonable agreement between travel times used in trip distribution and resulting from assignment. EPA continues to believe that these modeling attributes reflect the current consensus in the transportation and air quality planning professions on minimum acceptable modeling practices.

Option 3: Streamline Existing Modeling Attributes and Address Additional Attributes in Guidance. This option would streamline the existing conformity rule, but retain certain requirements that provide for minimum acceptable model performance.

The streamlined requirements would be as follows: (1) Network-based models must be validated against observed peak and off-peak ground counts for a base year that is not more than 10 years prior to the date of the conformity determination; (2) land use, population, employment, and other network-based modeling inputs must be based on the best available information and must be appropriate to the validation base year; (3) peak and off-peak travel demand and travel times must be provided, and a capacity-sensitive assignment methodology must be used; (4) the model(s) must use and document a logical correspondence between the assumed scenario of land development and use and the future transportation system for which emissions are being estimated; and (5) network-based models must be reasonably sensitive to trip-making changes due to changes in the cost, travel time, capacity, and quality of all travel choices, if the necessary information is available.

EPA would address the remaining attributes in modeling guidance that would be jointly issued and regularly updated by EPA and DOT. Conformity stakeholders would be involved in the development of this modeling guidance to encourage a wide exchange of ideas about current and available modeling practices. EPA believes that this process itself would ensure that the modeling guidance is a useful, effective tool in informing areas about available modeling improvements.

B. Adding Non-exempt Projects to the Plan/TIP Without Regional Analysis

1. Description of Proposal

This proposal would, under some circumstances, allow a transportation plan and TIP to be amended to include additional non-exempt projects without a full-scale regional emissions analysis based on network modeling. The alternate emissions analysis procedure would require the concurrence of the federal, state, and local air and transportation agencies. This flexibility would not become effective until EPA and DOT have completed their review and evaluation of alternate procedures that are suggested during the public comment period (see ''Request for Information for Guidance,'' below) and made this documentation publicly available. This proposal would still require a conformity determination for the plan/TIP amendment, including public participation, interagency consultation, and other relevant requirements of the transportation conformity rule. This proposal would only change the rigor of the supporting regional emissions analysis.

Under the existing rule, every plan/TIP and plan/TIP amendment requires a conformity determination based on a regional emissions analysis that meets the requirements of § 51.452/§ 93.130. The regional emissions analysis, which includes projects in the plan/TIP and all other regionally significant projects in the nonattainment or maintenance area, is used to demonstrate that the budget test and/or emission reduction tests are satisfied. Under § 51.452, certain areas are required to use network modeling to perform this regional emissions analysis.

This proposal would allow less rigorous analysis to demonstrate that the plan/TIP as amended satisfies the budget test and/or emission reduction tests. Subsequent plan/TIP conformity

determinations based on full regional emissions analysis would, of course, include the recently added projects, because regional emissions analysis must include all regionally significant projects that are planned or underway. Any plan/TIP conformity determination based on less rigorous analysis would not be considered a conformity determination for the purposes of § 51.400/§ 93.104, ''Frequency of Conformity Determinations,'' which require that conformity determinations be made no less frequently than every three years. The less rigorous analysis would not provide a complete consideration of projects in the transportation plan and TIP using the latest emissions projections and assumptions. The transportation plan and TIP would therefore have to be found to conform based on a full-scale regional emissions analysis (including network modeling, where required) at least every three years.

2. Rationale

EPA is proposing this change in response to stakeholder requests for this flexibility. Some stakeholders commented that it may be costly and resource-intensive to perform a full-scale regional emissions analysis to add a regionally significant project to a transportation plan and TIP. These stakeholders proposed that the conformity rule allow areas the flexibility to establish alternative procedures for regional emissions analysis that would demonstrate that an additional project, when considered with emissions projected for the conforming transportation plan and TIP, does not cause the plan/TIP to exceed the motor vehicle emissions budget and/or fail to satisfy the emission reduction tests. Stakeholders supporting this flexibility suggested that it is necessary only in extraordinary circumstances and would not be used on a routine basis. Other stakeholders expressed concern that such flexibility could be used to advance significant projects without the full scrutiny of the conformity process.

EPA agrees that there may be limited instances where the impact of regionally significant non-exempt projects on emissions from the currently conforming transportation plan and TIP could be determined without full-scale regional analysis, and that exceptional circumstances may arise where such flexibility is appropriate. However, this flexibility is to be exercised as an exception and not on a regular basis.

EPA would allow this flexibility to be used only after a review and evaluation of types of alternate procedures has been documented, because of the potential for this flexibility to undermine the integrity of the conformity process if improperly used. Conformity's purpose is to consider the long-term impacts of projects and to make transportation planning decisions within the context of all proposed projects, instead of on a project-by-project basis. In almost all cases, regional emissions impacts cannot be determined on a project-by-project basis or without considering the aggregate of projects in an area and the interactions among them. The conformity provisions were in part a response to the difficulty of assessing air quality impacts on a project-by-project basis. As a result, it is not clear what type of limited analysis would be appropriate and under what circumstances. Areas will need guidance to address these issues. This guidance will be provided in the review, evaluation, and documentation of alternate procedures that are suggested during the public comment period, through periodic updates of reasonable and available measures, and through the interagency consultation process.

Stakeholders proposed that the federal, state, and local transportation and air agencies should concur on each use of this flexibility. EPA agrees with such a concurrence requirement since there are not well-established, existing alternatives and because the transportation planning process and the conformity process should not be compromised if there is not agreement among all of the agencies that the existing circumstances warrant the use of this flexibility. As described in the conformity rule's consultation requirements, conflicts among state agencies or between state agencies and an MPO shall be escalated to the Governor if they cannot be resolved by the heads of the involved agencies.

EPA foresees instances where use of this flexibility would not be appropriate. For example, it would not be appropriate if planning assumptions have changed, or if other information indicates that the regional emissions analysis supporting the currently conforming transportation plan and TIP is not adequate to determine that the budget test and/or the emission reduction tests would be satisfied. It would also be inappropriate if the transportation plan and TIP amendment is not only adding projects, but deleting other projects and changing implementation dates in order to remain fiscally constrained. In this case, the plan/TIP amendment's scope would be too broad to justify a limited emissions analysis.

3. Request for Information for Guidance

EPA and DOT recognize that there may be some alternate procedures for determining the impact projects would have on regional transportation-related emissions that are more expeditious and less costly than a network-based analysis. As a result, EPA and DOT are requesting suggestions for procedures to add non-exempt projects to the plan/TIP without a complete network-based analysis. If documentation is available for these procedures, please provide it if possible.

Reasonable methods or approaches may be included in guidance. However, EPA and DOT believe that the flexibility for non-exempt projects (as described above) should not be finalized if reasonable alternate approaches have not been identified for determining the regional emissions impacts from individual transportation projects. Therefore, this flexibility would not be offered unless EPA and DOT receive comment that identifies such alternate methods or approaches.

Some stakeholders commented about the resources needed to perform a full-scale regional emissions analysis to add a regionally significant project. EPA and DOT are therefore requesting information in the following areas: (1) How often the need arises to add non-exempt projects between TIP update cycles; (2) the number of projects that may be delayed without this flexibility; (3) the full-scale network modeling process currently used for the regional emissions analysis to support conformity determinations (including number of model runs, number of emissions model runs, etc.); (4) the difference in effort required to add a single or limited number of projects as compared to a full-scale conformity analysis; and (5) which agencies are responsible for socioeconomic data development, travel modeling, and emissions modeling, including the percentage of each agency's involvement in conducting the conformity analysis.

VII. Consequences of SIP Disapproval

A. Description of Proposal

In today's action EPA proposes as a primary alternative regulatory language that specifies that following a 120-day grace period after final EPA disapproval of a control strategy SIP or maintenance plan without a protective finding, the only transportation projects that could be approved (and thus grandfathered from future conformity lapses) would be those included in the first three years of the currently conforming transportation plan and TIP (and exempt projects). No

new transportation plans, TIPs, plan/TIP amendments or projects (or projects in the out-years of the transportation plan and TIP) could be approved. If any single phase of a transportation project is included in the first three years of the transportation plan/TIP, all phases of the project would be able to proceed following a disapproval, provided that all phases of the project were included in the transportation plan/TIP conformity analysis. Conformity determinations are required to analyze entire projects rather than individual phases.

The ''freeze'' on new transportation plans, TIPs, and projects would be removed once an area submits another control strategy SIP or maintenance plan to replace the disapproved SIP, provided EPA does not find the motor vehicle emissions budgets inadequate during its 45-day review period. If such a replacement SIP does not become applicable to conformity determinations by the time Clean Air Act highway sanctions are imposed (two years after EPA's final disapproval), conformity would lapse, and no new project- level conformity determinations could be made, even for projects in the first three years of the currently conforming plan and TIP.

During the 120-day grace period, transportation plans, TIPs, and projects could be found to conform using the disapproved budgets (if no replacement SIP applies for transportation conformity purposes). This 120-day grace period is intended to allow areas to complete conformity determinations that were in process at the time of EPA's final disapproval.

Under both today's proposal and the existing conformity rule, consequences would occur following any EPA final disapproval action on a control strategy SIP or maintenance plan without a protective finding, even if the disapproval is limited or partial. The motor vehicle emissions budget is sufficient only if the SIP as a whole satisfies the Clean Air Act requirements for reasonable further progress, attainment, or maintenance. If one part of a SIP is disapproved without a protective finding (even if that part does not address mobile sources), then there is no overall strategy for reasonable further progress, attainment, or maintenance, and it is not possible to determine whether consistency with the motor vehicle emissions budget will result in a level of emissions consistent with reasonable further progress, attainment, or maintenance.

B. Request for Comment

Pending the opportunity to consider thoughtful comments from all interested parties, EPA is proposing today as a primary alternative the regulatory text discussed above because EPA believes it balances the conflicting goals articulated by stakeholders. EPA requests comment on how this proposal addresses stakeholder issues and concerns identified below. EPA also requests comment on whether other approaches are preferable, such as aligning the conformity lapse timeframe with the highway sanctions time clocks for SIP disapprovals without protective findings to make this process consistent with the conformity lapse process for other SIP failures. Alternatives to the primary option EPA is proposing today are described below. Depending on the public comment received, EPA may finalize one of these alternative approaches, instead of the primary alternative.

C. Discussion of Issue

Conformity stakeholders have raised the issue of the appropriate conformity consequences when EPA disapproves a control strategy SIP without making a protective finding. EPA disapproval of a SIP without a protective finding is essentially a finding that the SIP does not have identified strategies to reach attainment (or reasonable further progress or maintenance), and the motor vehicle emissions budget is not adequate to satisfy Clean Air Act requirements. Final EPA SIP disapprovals require full notice-and-comment rulemaking.

The November 1993 transportation conformity rule states that after a 120-day grace period following final EPA SIP disapproval, no new transportation plans, TIPs, or projects may be approved. Only previously approved projects (''grandfathered'' projects) and exempt projects may proceed. In other words, transportation plan/TIP conformity lapses. The lapse is removed when a new control strategy SIP or maintenance plan (including motor vehicle emissions budgets) is submitted to EPA.

Some stakeholders have suggested that conformity should never lapse as a result of a SIP failure before Clean Air Act highway sanctions are imposed, because highway sanctions (not transportation conformity) are the Clean Air Act mechanism for addressing SIP failures. To a considerable degree EPA agrees with this reasoning, and EPA has amended the conformity rule to align conformity lapse with highway sanctions imposition in the case of all SIP failures except disapproval without a protective finding.

However, there are substantive conformity issues with respect to SIP disapproval without a protective finding. If an area does not have sufficient adopted control strategies to attain the standards or make reasonable further progress towards attainment, should the area be committing funds to new transportation projects? If so, on what basis? Should it proceed with projects that already have been planned and upon which businesses and the public may already be relying in their own future plans, but stop creating new plans and expectations? In these cases, how would an area demonstrate that the transportation plan, TIP, or project would not increase the frequency or severity of existing violations, or contribute to new violations, or delay attainment?

These issues are particularly important in the context of the conformity flexibilities in today's proposal. As described in sections II. and III. of today's action, EPA is proposing that consistency with submitted SIP budgets would become the sole emissions-related conformity test for transportation plans and TIPs, even before EPA approves the SIP and confirms that consistency with its motor vehicle emissions budget is sufficient to achieve reasonable further progress, attainment, or maintenance. Some stakeholders are concerned that because a significant amount of time is likely to elapse between initial submission of the control strategy SIP and any subsequent EPA disapproval, a significant number of transportation projects could be found to conform (and thus grandfathered) on the basis of an ultimately unacceptable motor vehicle emissions budget before final EPA disapproval actually occurs. These stakeholders are concerned about irreversible commitments that might make Clean Air Act requirements increasingly difficult to meet.

Other stakeholders emphasize that the disruption to the ongoing transportation planning process should be minimized. They believe that people and businesses begin to rely on projects in an approved plan and TIP even though project-level conformity findings have not been made, and conformity lapse immediately upon EPA's final disapproval is unduly disruptive.

D. Discussion of Options

Stakeholders have identified a number of options to address the consequences of EPA SIP disapproval without a protective finding. These options address the concerns described

above to varying degrees. EPA is interested in receiving comments on the alternative options described below and may finalize one of these options, instead of the primary option described above.

1. No Project Approvals (Conformity Lapse) Beginning Immediately Upon EPA Final Disapproval Without a Protective Finding

Some stakeholders have suggested that no more projects should be approved (grandfathered) once EPA issues a final disapproval. However, these stakeholders generally accept that projects found to conform between submission and final disapproval should not be halted, even once the SIP has been disapproved. This option would minimize commitments that could ultimately be inconsistent with attainment or maintenance, until another SIP that would be a better basis for determining conformity is submitted to EPA.

2. Retain Existing Conformity Rule

As described above, the November 1993 transportation conformity rule allows transportation plans, TIPs, and projects to be approved for 120 days following EPA's final disapproval of a SIP without a protective finding. Following the 120-day grace period, no transportation plans, TIPs, or projects can be approved. This approach is similar to option 1 above, but the 120-day grace period helps reduce disruption to approvals that are underway at the time of EPA's final disapproval.

3. Allow Approval of Projects in the First Two Years of the Transportation Plan/TIP

Some stakeholders advocate allowing previously planned transportation projects to be approved and grandfathered, but not approving new transportation plans, TIPs, or projects until a new SIP has been submitted to EPA. For example, some stakeholders endorsed a proposal that no transportation plans, TIPs, or amendments should be found to conform after EPA's final disapproval of a SIP, and only those projects scheduled for implementation during the first two years of the TIP, and projects found by the MPO and the state air agency to contribute to emissions reductions, should be allowed to proceed.

This option is similar to that being proposed by EPA today as the primary alternative. This option prevents new commitments from being made, but allows projects previously planned to occur in the short term to proceed, in order to minimize disruption to the transportation planning process.

4. No Consequences Until Clean Air Act Highway Sanctions Are Applied

Other stakeholders advocate allowing new transportation plans, TIPs, and projects to be approved and grandfathered using the build/no-build test or the disapproved motor vehicle emissions budget until Clean Air Act highway sanctions are imposed. Highway sanctions under section 179 would be imposed two years following EPA's final disapproval unless the deficiency leading to the disapproval has been corrected prior to that time. These stakeholders believe that it is more consistent with the Clean Air Act to have Clean Air Act section 179 highway funding sanctions being the trigger for consequences of a SIP disapproval. This change would also simplify the conformity rule by having all conformity lapses associated with SIP failures occur when highway sanctions are imposed.

E. Rationale for Primary Option Being Proposed

EPA believes that the primary option it is proposing today (as described in section VII.A.) best balances the concerns expressed by stakeholders. EPA is proposing to allow projects in the first three years of the transportation plan/TIP to proceed, instead of those in the first two years, as suggested in option 3. Some conformity stakeholders expressed concern that restricting the ''grandfathering'' to the first two years of the transportation plan/TIP would be unduly disruptive to the transportation planning process, especially because the TIP normally addresses a minimum of three years. EPA believes that the primary option provides a better balance between the competing objectives of minimizing new commitments and minimizing disruption to the transportation planning process.

VIII. Mismatch in SIP/Transportation Plan Timeframe

A. Description of the Issue

The existing transportation conformity rule requires the conformity of transportation plans and TIPs to be demonstrated for the entire 20-year timeframe of the transportation plan. However, control strategy SIPs and maintenance plans generally address a significantly shorter timeframe. For example, attainment demonstrations are only required to address the years through the attainment year, and maintenance plans are only required to initially address a 10-year period (with a provision for a second 10-year appraisal).

For the years in the timeframe of the transportation plan that are not addressed specifically by a SIP, the existing conformity rule requires emissions to be consistent with the SIP motor vehicle emissions budget(s) for the last year for which the SIP defines control strategies and budgets. For example, before a maintenance plan has been submitted, emissions predicted for the years after the attainment year must be consistent with the attainment year budget(s). Emissions in years after the first maintenance plan must be consistent with the motor vehicle emissions budget(s) for the last year of that maintenance plan.

Several conformity implementers have commented that there should be a more flexible conformity test for the years that are not specifically addressed by the SIP. Conformity implementers have pointed out several difficulties caused by the existing transportation conformity rule's requirements for the ''out-years'' of the transportation plan.

First, there are generally no adopted control measures to address VMT growth in years that are not specifically addressed by the SIP. As a result, it becomes the burden of the conformity process—and potentially the MPO alone—to address long-term growth issues and offset emissions increases. Placing the burden on the MPO to offset emissions from long-term growth can be problematic because MPOs generally lack the authority to adopt and enforce areawide emission controls. In areas such as PM_{10} areas this problem is particularly acute, because motor-vehicle-related PM_{10} emissions are directly related to VMT. Technological improvements in the motor vehicle fleet over time do not significantly reduce motor vehicle PM_{10} emissions related to reentrained dust.

In addition, the existing conformity rule's requirement to use the budget established for the last year of the maintenance plan for all subsequent years poses special difficulties. In many areas, the motor vehicle emissions budget will decline over the 10 years of the first maintenance plan. This is generally because newer, cleaner cars will be added to the motor vehicle fleet as older cars are retired, so the emissions per VMT decrease. At the same time, emissions from stationary sources are often related to economic and population growth, and are thus projected to increase over time. As a result, many areas demonstrate maintenance of air quality standards with declining motor vehicle emissions

budgets and increasing stationary source emissions.

However, over time the effect of fleet turnover decreases, because all cars in the fleet eventually meet applicable standards. In addition, increases in VMT may begin to offset the emissions decreases resulting from fleet turnover. Thus, motor vehicle emissions generally are projected to increase in the years after the first 10-year maintenance plan, and the motor vehicle emissions budget established for the last year of that maintenance plan may in fact represent a low point in the motor vehicle emissions projected for the 20-year maintenance period. Requiring motor vehicle emissions in the years after the first maintenance plan to be consistent with the budget for the last year of that maintenance plan may be difficult without additional control measures for stationary or mobile sources.

B. Request for Comment

EPA is not proposing specific regulatory text to address this ''mismatch'' issue at this time. However, EPA requests comment on three options, and EPA proposes to include one of the options in the regulatory text of the final rule.

1. Existing Transportation Conformity Rule

The first option is to continue the existing conformity rule's requirements. According to the Clean Air Act, one of the purposes of conformity is to ensure that transportation improvements do not cause or contribute to new violations. The motor vehicle emissions budget for the attainment year represents the level of motor vehicle emissions that is consistent with attainment of the standard. Therefore, keeping motor vehicle emissions in future years equal to or less than that budget should ensure that motor vehicles will not cause or contribute to a new violation. If motor vehicle emissions increase above levels that the SIP identifies as necessary for attainment, it may be difficult to state that a new violation would not result, as conformity requires.

Regarding the comments that the existing conformity rule inappropriately places the burden on the MPO to address long-term growth issues, it is in fact an important goal of conformity to focus attention on the long-term impacts of transportation investments and policies. To the extent that an area has not reconciled the impacts of growth and transportation policy with air quality goals, it is appropriate that conformity provide the forum and impetus for state and local governments to do so. Although the MPO may not itself have the authority to adopt and enforce necessary measures, conformity is determined through an interagency process which includes the state and local governments which do have that authority. It is appropriate that the long-term growth issues affecting a local area be addressed through the cooperation of state and local air and transportation agencies. The fact that the MPO has legal responsibility to determine conformity does not mean it alone must develop and implement the additional control measures that are necessary. The state also shares an interest in developing conforming metropolitan transportation plans and TIPs and would be expected to share responsibility for facilitating conformity.

Maintaining the existing conformity rule's requirements regarding the applicability of motor vehicle emissions budgets for future years would also encourage the SIP process to address longer timeframes, which is ultimately the preferable solution. Doing so should avoid costs and burdens of not addressing long-term issues now. The difficulties associated with demonstrating conformity in years that are not addressed by the SIP would be reduced if the SIP established acceptable motor vehicle emission levels for such future years. This has already occurred in some areas.

The existing conformity rule already has some provisions to address the difficulties associated with using the budget for the last year of the maintenance plan for subsequent years. For example, the maintenance plan could establish larger motor vehicle emissions budgets for years after the last year of the maintenance plan by projecting motor vehicle emissions and emissions from other source categories in future years. Provided the projected total emissions are less than the total emissions in a previous year with clean data, the motor vehicle emissions projections could be used to establish a motor vehicle emissions budget. If the projected total emissions are less than the total emissions in a previous year with clean data, the difference (''safety margin'') could also be applied to the motor vehicle emissions budget.

2. Emission Reduction Tests

A second option would be to require the emission reduction tests (''build/no-build test'' and less-than-1990 test) for demonstrating conformity in years not addressed by submitted or approved control strategy SIPs or maintenance plans. Demonstrating conformity for years later than those addressed by SIPs is in some ways analogous to the situation of demonstrating conformity for years before SIPs are submitted, that is, no budget has been specifically developed for assessing conformity in such years. The Clean Air Act allows for ''contribution to annual emission reductions'' to serve as the test of conformity in the latter case, so by extension, it could be argued that such a test is also appropriate for years later than those addressed by SIPs. The Clean Air Act requirement for consistency with emissions in SIPs could be argued to apply only for those years that are specifically addressed by the SIP.

Although this option provides more flexibility than the existing rule for emissions increases due to population and economic growth, it has several disadvantages. First, satisfying the emission reduction tests would not ensure that motor vehicle emissions are at a level consistent with attainment or maintenance. Although the conformity test would ensure that motor vehicle emissions are no greater than they would have been without further transportation improvements, the focus is not on attainment or maintenance of air quality standards. As a result, the impact of long-term growth on attainment and maintenance will not necessarily be addressed.

The Clean Air Act requires a second 10-year maintenance plan to be submitted eight years after an area's redesignation to attainment, so the SIP process in redesignated areas will ultimately address the emissions in the years after the first 10-year maintenance plan. In the case of areas that have not yet been redesignated, however, allowing motor vehicle emissions to increase above the attainment year budget may make it increasingly difficult to develop a SIP demonstrating maintenance, and thus may delay or complicate redesignation of such areas to attainment.

Finally, conformity implementers and other interested parties have commented that the emission reduction tests are not meaningful indicators of air quality impacts, particularly because transportation modeling and emission factor modeling are often not sufficiently precise to determine significant differences between ''build'' and ''no-build'' scenarios. Experience to date has found that the emission reduction tests are frustrating and difficult to explain because they do not address the performance-oriented goals of attainment and maintenance. Although practical alternatives have not been identified for use during the period before SIPs have been developed, for years later than those addressed by SIPs,

the previously established motor vehicle emissions budgets are available.

3. Default Motor Vehicle Emissions Budget

A third option is to maintain the existing rule's requirements for the years after the attainment deadline and before a maintenance plan has been submitted, but to allow a default motor vehicle emissions budget for the years outside the maintenance plan's timeframe. Instead of requiring the motor vehicle emissions budget for the last year of the maintenance plan to continue to apply for subsequent years, the motor vehicle emissions budget for subsequent years could be the motor vehicle emissions in the year of redesignation.

Like the emission reduction tests option, this option would not ensure that motor vehicle emissions are consistent with maintenance of air quality standards. Without considering emissions from sources other than motor vehicles, there is no assurance that the motor vehicle emissions in the year of redesignation will also be consistent with continued maintenance of the standard in future years. However, this problem could be at least somewhat reduced with additional features to this option. For example, the rule could require the default budget to be established in the maintenance plan and accompanied by some type of demonstration that when the default motor vehicle emissions budget is considered together with expected growth in area and stationary source emissions, the standard will be maintained.

The default emissions budget option may be preferable to the emission reduction tests option for the years after those addressed by maintenance plans for two reasons. First, conformity implementers have expressed a preference for budget tests instead of the more abstract emission reduction tests. Second, unlike the emission reduction tests option, this option would provide a cap on motor vehicle emissions growth. Although the cap is not necessarily tied to maintenance, it does not allow emissions due to population and economic growth to revert back to 1990 levels, as the emission reduction tests allow. As a result, the conformity process could still provide significant protection for the public while providing the impetus for serious consideration of long-term growth effects.

Unlike the emission reduction tests option, this option would maintain the existing rule's requirements (i.e., the attainment budget would continue to apply for the years after the attainment deadline) until a maintenance plan is submitted. This will help prevent delays in attainment and/or redesignation.

Allowing conformity to be demonstrated using a default emissions budget that is not part of an overall maintenance strategy that addresses all emissions sources could be considered inconsistent with the Clean Air Act section 176(c) and the conformity rule's other interpretations of those provisions. However, it is also possible to argue that such an allowance is reasonable and defensible in the special circumstance of demonstrating conformity for years that have not yet been addressed by the maintenance plan.

For example, the legislative history of the Clean Air Act reveals a specific choice to require maintenance plans to address 10-year increments rather than an entire 20-year period. It could therefore be argued that it is not conformity's responsibility to ensure maintenance over a 20-year period; provided the transportation community keeps motor vehicle emissions constrained to some level previously associated with maintenance, future maintenance plans could address emissions from other sources and revise motor vehicle emissions budgets as necessary for an overall maintenance strategy. It could also be argued that the Clean Air Act's Prevention of Significant Deterioration requirements are intended to address growth in non-mobile source emissions in years not addressed by maintenance plans, and that EPA can issue SIP calls if growth in non-mobile source emissions threatens maintenance.

IX. Public Participation

A. Description of the Proposal

This proposal would clarify the timeframe within which information must be provided for public access under the public participation requirements in the existing conformity rule. The proposal would specify that affected agencies must provide public access to information considered by the agency in making transportation plan and TIP conformity determinations at the beginning of the designated public comment period and prior to taking formal action on conformity determinations. This proposal would define the information to include all technical and policy information considered by the agency in supporting conformity determinations.

This proposal would continue to reference and be consistent with DOT's metropolitan planning regulation (23 CFR 450.316(b)), which, among other things, requires at least a 30-day comment period in serious and above nonattainment areas. Agencies affected by this proposal would be referred to DOT's January 1995 guidance, ''Public Involvement and Questions and Answers'' (60 FR 5508–5512), for specific identification of the types of information to be provided to the public. EPA expects that affected agencies would refer to this guidance in providing information for public comment. The guidance specifies input assumptions such as population projections, land use projections, fares, tolls, levels of service, the structure and specifications of travel demand and other evaluation tools.

Since information supporting conformity determinations is stored in many forms, EPA interprets that this proposal's requirement would apply to information in written, graphic, and electronic form. Under this proposal, any charges imposed by affected agencies for public inspection and copying would be required to be consistent with the fee schedule in 49 CFR 7.95, which EPA believes would ensure reasonable public access to the information. EPA also notes that under the DOT metropolitan planning regulations, each MPO conducts public involvement under its own custom-tailored public involvement procedures. These procedures describe how the MPO intends to meet the performance standards of the conformity rule and metropolitan planning regulations.

B. Discussion of Proposal

EPA is proposing this clarification to address stakeholder concerns that public participation is hindered when public access to information relied on for conformity determinations is not provided in enough time to allow for adequate public involvement. EPA agrees that public access to all of the information considered by the agency at the beginning of the public comment period is critical to ensuring effective public participation in the conformity process.

In its ''Public Involvement and Questions and Answers'' guidance, DOT emphasizes that an effective public involvement process should provide for an open exchange of information and ideas between the public and transportation decisionmakers, and as an overall objective, an area's public involvement process should be proactive, provide complete information, timely public notice, full public access to key decisions, and opportunities for early and continuing involvement. EPA believes that this

proposal would not only be consistent with these objectives, but that it would further the purposes emphasized in the guidance.

EPA does not believe that this proposal would be burdensome for affected agencies since it would only require that agencies provide public access to information already in their possession. This proposal would not require the affected agencies to edit, summarize existing files, or to compile new files beyond those already prepared as a part of the plan and TIP development process.

X. Interagency Consultation

This proposal includes several new provisions which require interagency consultation, including the choice of conformity tests and modeling methodology for rural areas; the establishment of a ''default budget'' in clean data areas; and the addition of non-exempt projects to the transportation plan/TIP without full regional emissions analysis. EPA is not proposing to amend § 51.402/§ 93.105 (''Consultation'') to add these consultation needs to the list of specific processes that must be included in the conformity SIP's consultation procedures. EPA believes that it is clear that consultation procedures must be developed in order to use these new provisions. As a result, EPA does not believe that the complexity resulting from adding items to § 51.402 is justified. Furthermore, the proposed provisions involving additional consultation procedures are for the most part optional flexibilities for unique situations, so consultation procedures to implement these flexibilities will not be relevant for all conformity SIPs.

However, EPA emphasizes that interagency consultation on these specific provisions is a necessary part of their implementation. EPA recommends that in order to facilitate future conformity determinations, areas should develop appropriate consultation procedures as soon as possible if they expect to use these provisions.

XI. Streamlining and Clarification

This proposal includes numerous wording and organizational changes that would streamline and clarify the existing transportation conformity rule. Although these changes affect most sections of the existing transportation conformity rule, highlights are discussed below.

A. Frequency of Conformity Determinations

1. Three-year Requirement

This proposal would clarify that both the MPO and DOT must redetermine conformity of transportation plans/TIPs within three years of DOT's transportation plan/TIP conformity determination. The existing transportation conformity rule is not explicit regarding the start of the three-year clock and which agencies' conformity determinations must be completed before expiration of that clock. This clarification is consistent with implementation practice to date and would help reduce confusion and ambiguity for future implementers.

2. Triggers for Redetermination

This proposal would streamline the paragraph that describes which events trigger an 18-month clock for redetermination of conformity. This proposal would also move § 51.448(a)(1)/§ 93.128(a)(1), as amended on November 14, 1995, so that the requirement to determine conformity within 18 months of the initial submission of a control strategy SIP or maintenance plan is in the frequency section with the other triggers for conformity redetermination. Although the substance of the requirement is unchanged, the restructuring improves the flow and clarity of the rule.

The relocation of § 51.448(a)(1) highlights the fact that a conformity determination is required within 18 months of both the initial submission and final EPA approval of a control strategy SIP or maintenance plan. Both submission and approval trigger a redetermination of conformity, because it is not uncommon for the SIP to change between initial submission and final approval. If conformity was determined to the initial SIP submission and the SIP did not change between initial submission and final approval, the requirement to determine conformity after final approval could be satisfied without new regional emissions analysis.

3. Requirement for TIP Conformity Within Six Months of Transportation Plan Conformity

This proposal would clarify existing § 51.400(a)(3)/§ 93.104(a)(3) by specifying that the TIP must be determined by DOT to conform within six months of DOT's conformity determination on a new or revised transportation plan. The existing requirement starts the six-month clock with the date of adoption of the plan.

EPA received comment suggesting that the six-month limit between transportation plan and TIP conformity determinations is not necessary and should be removed. EPA believes that this requirement should be retained because of ISTEA's (and hence, conformity's) expectation that the TIP will flow from, and be consistent with, the transportation plan. The conformity rule requires TIP conformity to be based on a consideration of all projects in the 20-year timeframe of the transportation plan. As a result, changes to the transportation plan should be reflected in the TIP's conformity determination in a timely manner.

EPA expects that in almost all cases, the plan and TIP will be developed concurrently and one regional emissions analysis will be performed to support both conformity determinations. In cases where the transportation plan and TIP are not developed concurrently, EPA believes the six-month requirement is critical to ensure that, given the changes to the transportation plan, projects from the TIP would still result in a level of regional emissions in 20 years that would not cause a new violation, worsen existing violations, or delay timely attainment.

B. Criteria and Procedures for Determining Conformity of Transportation Plans, Programs, and Projects: General

This proposal would consolidate several parts of the existing transportation conformity rule into § 51.410/§ 93.109 in order to create a section that provides a comprehensive overview of when and in what circumstances the budget test, emission reduction tests, and hot-spot tests are required. The section would have separate paragraphs for ozone, CO, PM_{10}, and NO_2 areas and isolated rural areas so that the rule is easier to use and so that the conformity implications of Clean Air Act requirements and classifications that are unique to each pollutant are specifically addressed.

This consolidation would allow the elimination of existing § 51.464/§ 93.136 (''Special provisions for nonattainment areas which are not required to demonstrate reasonable further progress and attainment'') and § 51.452(d)/§ 93.130(d) (''Projects not from a conforming plan and TIP in isolated rural nonattainment and maintenance areas''). The provisions for special situations would be discussed in the same place as provisions for other areas, thus making these provisions easier to locate and improving the clarity and user-friendliness of the rule.

As discussed in section II., the existing rule's classification system of ''Phase II interim period,'' ''transitional period,'' and ''control strategy period'' would be eliminated.

C. Latest Planning Assumptions

This proposal would clarify that conformity determinations must use the latest existing information regarding the effectiveness of all relevant SIP control measures, including TCMs, that have already been implemented. This would reduce confusion regarding what emission reduction credit should be assumed from vehicle inspection and maintenance programs that are included in approved SIPs and that are already being implemented.

D. Consultation Criterion

This proposal would clarify § 51.416/§ 93.112 (''Criteria and procedures: Consultation''), which is the section requiring conformity to be determined according to the consultation procedures of the rule, the conformity SIP, and DOT's planning regulations.

This proposal would remove the reference to the MPO so that it is clear that rural areas must also abide by interagency and public consultation requirements. In addition, this proposal removes ambiguous language that could imply that areas are not required to comply with public participation procedures after the conformity SIP is approved.

E. Hot-spot Tests

This proposal would consolidate and streamline existing §§ 51.424 and 51.434 (§§ 93.116 and 93.121), which address localized CO and PM_{10} violations (hot spots). The two sections would be combined, and paragraph (c) of each of these sections would be moved to the section addressing procedures for determining localized CO and PM_{10} concentrations (hot-spot analysis). This would reduce confusion regarding the distinction between the two hot-spot tests and streamline the discussion of both the conformity tests and the methodological requirements.

F. Compliance With PM_{10} Control Measures

This proposal would clarify the existing requirement of § 51.426/§ 93.117 for SIP PM_{10} control measures to be included in the project's final plans, specifications, and estimates. Because the final plans, specifications, and estimates are generally not developed until after the project's conformity determination, it is problematic for the existing rule to make the plans, specifications, and estimates a condition of the project-level conformity determination. This proposal would require the conformity determination to include a written commitment to include SIP PM_{10} control measures in the project's plans, specifications, and estimates. Such commitments would be enforceable, as required by existing § 51.458/§ 93.133 (''Enforceability of design concept and scope and project-level mitigation and control measures'').

G. Budget Test

This proposal would combine existing §§ 51.428–51.432 (§§ 93.118–93.120) into one streamlined section that describes the budget test for the transportation plan, TIP, and project not from a conforming plan and TIP. As described in section III. of this preamble, the implementation of the budget test and the years for which budgets apply would be clarified.

H. Emission Reduction Tests

This proposal would combine existing §§ 51.436–51.446 (§§ 93.122–93.127), which describe the tests for emission reductions in the interim period for ozone, CO, PM_{10}, and NO_2 areas, into one streamlined section that addresses all pollutants and the transportation plan, TIP, and project not from a conforming plan and TIP. This would avoid the repetition of the definitions of the ''Baseline'' and ''Action'' scenarios and improve the readability of the transportation conformity rule.

This proposal would provide that the first analysis year shall be no more than five years beyond the year in which the conformity determination is being made. The existing conformity rule requires the first analysis year to be 1995 in CO nonattainment areas and 1996 in ozone nonattainment areas. This requirement is obviously no longer appropriate, because conformity is not intended to be assessed retrospectively.

This proposal would also modify the definition of the ''Baseline'' scenario so that only projects that come from the first year of the previously conforming transportation plan/TIP are required to be included in the ''Baseline'' scenario. The existing conformity rule requires projects from the first three years of the previously conforming transportation plan/TIP to be included in the ''Baseline'' scenario. The proposed modification is intended to correct the perverse incentive that the existing requirement creates for areas to withhold projects with air quality benefits. Some stakeholders have commented that because the air quality benefits of projects in the second and third year of the TIP are included in the ''Baseline'' after the initial TIP conformity determination, areas are holding back some projects for use in future ''Action''/''Baseline'' comparisons.

I. Transition From the Interim Period to the Control Strategy Period

Because the proposal would no longer use the terms ''interim period'' and ''control strategy period,'' this proposal would consolidate and streamline existing § 51.448/§ 93.128 and better integrate its provisions into the rest of the transportation conformity rule.

Under the proposal, this section would address only the conformity consequences of various SIP failures. This section would streamline the existing requirements regarding conformity lapse resulting from SIP failures, as amended August 7, 1995, and November 14, 1995. The term ''protective finding'' would be included in the definitions section in order to decrease the wordiness of the requirements and improve the readability of the rule.

Some of the existing requirements of § 51.448 would be incorporated in the frequency section, the general overview of the criteria and procedures, and the budget test. Existing paragraphs (e) through (i) would be eliminated. Existing § 51.448(e) requires consultation on individual capacity-increasing projects in areas that have not yet submitted control strategy SIPs. Because all areas that are already required to submit control strategy SIPs have made such submissions, EPA believes that the requirements of paragraph (e) are no longer necessary.

Existing § 51.448(f) describes conditions under which new regional emissions analysis is not necessary in order to determine conformity to a newly submitted control strategy SIP. EPA continues to believe that new regional emissions analysis would not be necessary under the conditions described in paragraph (f). However, EPA does not believe that this provision needs to be included in the regulatory text, because the provision is not commonly used and EPA believes the provision is sufficiently well understood.

Existing paragraphs 51.448 (g) through (i) are no longer relevant given the other changes to the transportation conformity rule proposed in this notice.

J. Procedures for Determining Regional Transportation-Related Emissions

This proposal would generally streamline and clarify existing § 51.452/§ 93.130. Some of the clarifications are highlighted below.

1. Credit for Delayed Measures

This proposal would clarify that if TCMs or any other measures in the approved SIP are delayed beyond the scheduled date, emission reduction credit may not be included in the emissions analysis until implementation is assured. This clarification would ensure that the requirements for latest planning assumptions and restrictions on assuming credit for regulatory measures are logically and consistently applied. As described in the discussion of the clarification to the ''Latest planning assumptions'' section, broadening discussion of TCMs to include other SIP measures would reduce confusion regarding emission reduction credit for vehicle inspection and maintenance programs.

2. Credit for Future Measures

This proposal would streamline and clarify the conditions under which emission reduction credit from future regulatory measures could be assumed. In addition, the proposal would add language regarding control measures that do not need a regulation in order to be implemented, but are not included in the transportation plan/TIP or the SIP. This language is intended to address measures such as increased street sweeping or street sanding specifications, which are external to the usual transportation planning process and which require some form of commitment that may not be explicitly regulatory or included in the SIP.

This proposal would allow emission reduction credit from such measures to be assumed if the conformity determination includes written commitments to implementation of the measures by appropriate entities (e.g., government agencies, private project sponsors). The conformity SIP would have to provide that written commitments that are included in conformity determinations are enforceable under the SIP. This language regarding enforceability is similar to that in existing § 51.458/§ 93.133 (''Enforceability of design concept and scope and project-level mitigation and control measures'') and that included in the general conformity rule (58 FR 63214, November 30, 1993).

The proposed additional language would reduce confusion regarding these types of control measures and would allow more explicit flexibility for these measures to be developed and credited in the conformity process. The proposal would require written commitments to be included as part of the conformity determination, but would not require the commitments to be specifically included in the SIP. By making such commitments enforceable under the SIP as a general matter, the SIP would not have to be revised to include each specific commitment.

The proposal would also allow regional emissions analyses to include emission reductions from projects, programs, or activities that are committed to in the control strategy SIP submission or the maintenance plan submission, similar to the existing conformity rule's § 51.452(a)(4). Consistent with EPA's SIP policy, SIP commitments must include a demonstration that the agency making the commitment has authority to implement the measure and that adequate personnel and funding are available for implementation.

3. Highway Performance Monitoring System (HPMS)

This proposal would clarify existing § 51.452(b)(2)/§ 93.130(b)(2) to specify that although HPMS estimates of VMT shall be considered the primary measure of VMT in certain cases, locally developed count-based programs and other variations from the procedure described in the conformity rule are permitted subject to the interagency consultation process. This paragraph applies to serious, severe, and extreme ozone nonattainment areas and serious CO nonattainment areas with an urbanized area population over than 200,000.

In its experience implementing the transportation conformity rule since 1993, EPA has received several questions regarding what should be used as the measure of VMT in areas that are not serious or above ozone or CO areas. These areas may use HPMS (including the factoring procedure described in existing § 51.452(b)(2)/§ 93.130(b)(2)) or other locally developed programs and procedures, subject to the interagency consultation process.

4. Reliance on Previous Regional Emissions Analysis

This proposal would consolidate in the section on procedures for regional emissions analysis the discussion of circumstances under which new regional emissions analysis may not be necessary. This discussion is currently included in the description of the budget test for TIPs and projects not from a conforming plan and TIP (§ 51.430/§ 93.119 and § 51.432/§ 93.120). This change would streamline these budget test sections and allow a simpler discussion of what must be demonstrated in order to satisfy the budget test.

K. Procedures for Determining Localized CO and PM_{10} Concentrations (Hot-spot Analysis)

This proposal would restructure the procedural requirements for hot-spot analysis in order to clarify that the hot-spot tests should be satisfied using EPA ''Guideline'' models in specified cases and in other cases may be satisfied using other quantitative or qualitative methods. This proposal would retain the existing rule's description of what projects should have hot-spot analysis according to EPA's ''Guideline'' models, but would clarify that other methods may be agreed upon through the interagency consultation process and with the approval of the EPA Regional Administrator.

EPA is willing to consider methods that identify different thresholds for determining which projects would require EPA ''Guideline'' models. For example, although the existing rule requires all projects affecting intersections at Level-of-Service D, E, or F to be quantitatively modeled using EPA ''Guideline'' models, an area may develop other thresholds for quantitative analysis based on delay times, traffic volume, queue lengths, background CO levels, and/or receptor locations. EPA will consider alternative methods for thresholds provided they are sufficient to determine that projects will not cause or contribute to new CO violations or increase the frequency or severity of existing CO violations (as described by the hot-spot criterion).

In addition, if an individual project affects multiple intersections, EPA is willing to approve procedures that require quantitative modeling initially only for those intersections with the greatest potential for CO violations. If quantitative modeling of those intersections does not predict CO violations, the other intersections affected by the project would not have to be quantitatively modeled.

L. Enforceability of Design Concept and Scope and Project-Level Mitigation and Control Measures

This proposal would clarify existing § 51.458/§ 93.133 by stating that a waiver of mitigation measures is subject to the conformity rule's public participation requirements for project-level conformity determinations. The conformity rule requires public involvement in conformity determinations for projects where otherwise required by law (e.g., the National Environmental Policy Act (NEPA)). This clarification is consistent with EPA's original intent for a waiver of mitigation measures to be permitted

through a process similar to the original conformity determination. This clarification is in response to the May 26, 1994, Petition for Reconsideration by the Environmental Defense Fund, the Natural Resources Defense Council, and the Sierra Club Legal Defense Fund.

M. Exempt Projects

This proposal would clarify Table 2 of existing § 51.460/§ 93.134 by specifying that the advance land acquisitions that are exempt are those emergency/hardship acquisitions provided for by 23 CFR 712.204(d).

As described in the preamble to the November 1993 conformity rule (58 FR 62213), the advance land acquisitions referred to in Table 2 are those ''parcels that are acquired to protect a property from imminent development and increased costs which would tend to limit a choice of transportation alternatives, or are acquired to alleviate particular hardship to a property owner at his or her request. This is only allowed in emergency or extraordinary cases, and only after the state department of transportation has given official notice to the public that a preferred highway or transit location has been selected, held a public hearing, or provided an opportunity for a public hearing.''

This proposal would make this intention clearer in the rule by providing the specific citation that enables this type of hardship acquisition and protective buying.

XII. TCM Flexibility

During the 1995 spring stakeholder meetings, EPA made a commitment to provide sample language for a SIP mechanism that would allow substitution of TCMs in a previously approved SIP without additional EPA approvals. As EPA indicated at that time, EPA believes that such a substitution mechanism is possible under existing EPA SIP policy, and no conformity rule amendment is necessary. As a result, EPA is not proposing language addressing TCM flexibility in today's action.

EPA will be drafting model SIP language and distributing it to conformity stakeholders for comment.

XIII. PM_{10} Hot Spots

Section 51.454(d) (93.131(d)) of the existing conformity rule requires quantitative PM_{10} hot-spot analysis in certain cases, but states that the requirements will not take effect until EPA releases modeling guidance and announces in the Federal Register that the requirements are in effect.

EPA has not yet released guidance on dispersion modeling for PM_{10} hot spots due to transportation projects. As a result, the requirements for quantitative PM_{10} hot-spot analysis are not currently in effect.

EPA has received comment requesting that these requirements should continue to be deferred until research that is underway by other organizations has been completed. For example, several PM_{10} studies are being sponsored by the California Air Resources Board and the California Department of Transportation.

EPA hereby announces its intention to delay the further development and issuance of its PM_{10} hot-spot modeling guidance pending the completion of research by organizations external to EPA. EPA does not intend to issue PM_{10} hot-spot modeling guidance before 1998. As a result, the requirements of existing § 51.454(d)/§ 93.131(d) will continue to be deferred until such time as EPA releases modeling guidance and announces in the Federal Register that the requirements are in effect.

XIV. Signalization Projects

EPA has received several comments suggesting that signalization projects, including areawide traffic signal synchronization projects and automated traffic surveillance and control projects, should be exempt from transportation conformity requirements. However, for the reasons described below, EPA is not proposing to change the exempt project lists (Tables 2 and 3 of the conformity rule) to exempt signalization projects.

A. Background

The transportation conformity rule does not require conformity determinations for certain types of projects. These ''exempt'' projects are listed in Table 2 of the conformity rule. In contrast to other transportation projects, exempt projects can proceed toward implementation even if a currently conforming transportation plan or TIP is not in place. These projects are exempt from conformity requirements because EPA considers them to have a neutral or de minimis impact on air quality. EPA does not exempt projects that could have regional impacts—even if those impacts may be positive—because EPA believes that regionally significant projects must be analyzed together, in the context of all other regionally significant projects. In this way, the interactions among projects may be considered, and there is a meaningful estimate of regional emissions that can be compared to the SIP's motor vehicle emissions budget.

In addition to the Table 2 projects that are exempt from conformity requirements, the transportation conformity rule also exempts certain projects from regional emissions analysis. These projects, which are listed in Table 3 of the conformity rule, are not required to be included in the regional emissions analysis for the transportation plan and TIP, and can proceed toward implementation even if a currently conforming transportation plan or TIP is not in place. However, conformity determinations are required for these projects, and the local effects of these projects on CO and PM_{10} concentrations must be considered in CO and PM_{10} nonattainment and maintenance areas.

The existing transportation conformity rule exempts intersection signalization projects at individual intersections from regional emissions analysis, as indicated in Table 2.

B. Comments Supporting Exemption of Signalization Projects

EPA has received comments that advocate the exemption of signalization projects because of positive air quality and congestion mitigation impacts of signalization projects and because of the implementation delays that may result from conformity requirements.

For example, some commenters state that signalization projects decrease emissions by reducing acceleration, deceleration, and idling. They cite studies of certain signalization efforts that indicate significant reductions in CO, VOC, and NO_x emissions. In addition, they state that improved efficiency of the roadway network benefits buses and high occupancy vehicle (HOV) users.

In addition, some commenters support exempting signalization projects in order to avoid delays that could result from the requirement for these projects to be included in the transportation plan and TIP's regional emissions analysis. Some commenters expressed concern that signalization projects could be delayed for up to a year while going through conformity analysis.

C. Rationale For Decision Not To Exempt Signalization Projects

EPA is not proposing to exempt signalization projects from conformity requirements because some of the projects may be complex, regionally significant projects whose emissions impacts must be assessed in the context of all regionally significant projects. For signalization projects that are not regionally significant, options exist to decrease the analysis burden and

potential delay of the conformity requirements, as described below.

As described above, EPA's list of exempt projects is intended to include only those projects with neutral or de minimis emissions impacts. The types of signalization projects that commenters suggest exempting are clearly not de minimis. For example, some signalization projects are areawide synchronizations that affect hundreds of intersections. Even the more limited signalization projects are often complex projects associated with roadway construction and improvement. Traffic signalization projects are not always limited to simple upgrades of hardware or installation of new signals.

In addition, signalization projects cannot generally be considered de minimis because they may affect traffic flow on a regional level. The emissions impacts may be positive or negative depending on the pollutant of concern, the speeds on the affected roads, and the effects on other roads in the network. For example, improved traffic flow and corresponding increases in traffic speed may reduce CO emissions, but may increase NO_X emissions in certain speed ranges. PM_{10} emissions may also increase. Significant changes in travel time may redistribute travel on other roads and affect mode choice. These effects need to be considered at a regional level, and the cumulative emissions impacts cannot be qualitatively determined.

EPA recognizes that not all signalization projects at multiple intersections are regionally significant, particularly if they affect a small number of miles in a large metropolitan area, or if an area's modeling capabilities are not sensitive to the more subtle regional effects of signalization projects. The existing conformity rule allows projects that are not regionally significant to be amended into the transportation plan and TIP without a new regional emissions analysis, if the regional emissions analysis supporting the currently transportation plan and TIP is still valid (e.g., planning assumptions have not changed). As a result, EPA believes that there are already sufficient opportunities to minimize the analysis burden and potential project implementation delays in cases where the signalization projects are relatively simple.

EPA considered trying to identify a threshold for determining which signalization projects at multiple intersections would not be considered regionally significant, so that these projects could be included in Table 3's list of projects that are exempt from regional emissions analysis. However, EPA decided that this approach would be unnecessarily complex and unlikely to provide a threshold that was appropriate for all areas. Areas currently have the discretion to determine which projects are regionally significant through the interagency consultation process, and thus have sufficient flexibility to minimize the analysis burden associated with signalization projects where appropriate.

Finally, although EPA agrees that the conformity process should minimize project implementation delays as much as possible, EPA does not believe the delays associated with regionally significant signalization projects are unreasonable. If signalization projects are identified at the time the transportation plan and TIP are being developed, they can be included in the transportation plan and TIP's regional emissions analysis initially, and implementation delays should not occur. In many instances TIPs are developed annually. If transportation plan/TIP amendments between TIP cycles can be avoided with improved planning, implementation delays could be reduced.

XV. Conformity SIPs

Section 51.396(a) of the existing conformity rule (as amended November 14, 1995) requires conformity SIP revisions to be submitted to EPA within 12 months after the date of publication of final amendments to the conformity rule. As a result, when EPA takes final action on today's proposal, conformity SIP revisions consistent with that final action will be due to EPA within 12 months.

As specified in § 51.396(b) of the conformity rule, after EPA approves a conformity SIP revision, the federal conformity rule does not govern conformity determinations. Therefore, for areas whose conformity SIP revision has already been approved by EPA, the final amendments that will result from today's proposal will not be effective until they are included in the conformity SIP revision and EPA approves that SIP revision.

XVI. Public Hearing

Anyone who wants to present testimony about this proposal at the public hearing (see **DATES**) should, if possible, notify the contact person (see **FOR FURTHER INFORMATION CONTACT**) at least seven days prior to the day of the hearing. The contact person should be given an estimate of the time required for the presentation of testimony and notification of any need for audio/visual equipment. A sign-up sheet will be available at the registration table the morning of the hearing for scheduling those who have not notified the contact earlier. This testimony will be scheduled on a first-come,first-serve basis to follow the previously scheduled testimony.

EPA requests that approximately 50 copies of the statement or material to be presented be brought to the hearing for distribution to the audience. In addition, EPA would find it helpful to receive an advance copy of any statement or material to be presented at the hearing at least one week before the scheduled hearing date. This is to give EPA staff adequate time to review such material before the hearing. Such advance copies should be submitted to the contact person listed.

The official records of the hearing will be kept open until the close of the comment period to allow submission of rebuttal and supplementary testimony. All such submittals should be directed to the Air Docket, Docket A–96–05 (see **ADDRESSES**). The hearing will be conducted informally, and technical rules of evidence will not apply. A written transcript of the hearing will be placed in the above docket for review. Anyone desiring to purchase a copy of the transcript should make individual arrangements with the court reporter recording the proceeding.

XVII. Administrative Requirements

A. Administrative Designation

Executive Order 12866

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 otherwise 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;

(4) Raise novel 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 this action raises novel legal or policy issues arising out of legal mandates, the President's priorities, and the principles set forth in the Executive Order. 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. Reporting and Recordkeeping Requirements

This rule does not contain any information collection requirements from EPA which require approval by OMB under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*

The information collection requirements of EPA's Transportation Conformity Rule and these amendments to it are covered under the Information Collection Request of the Department of Transportation entitled ''Metropolitan and Statewide Transportation Planning'', approved by OMB under the Paperwork Reduction Act through 11/96, with OMB Control Number 2132–0529. Send any comments on the recordkeeping and reporting requirements of Transportation Conformity to:

Mr. Sean Libberton, US Department of Transportation, TPL11, 400 7th Street, SW., Washington, DC 20590,

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for EPA/OAR, Room 10202, 725 17th Street, NW., Washington, DC 20503.

In any correspondence please refer to OMB Control Number 2132–0529.

C. Regulatory Flexibility Act

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 today's regulations will not have a significant impact on a substantial number of small entities. This regulation affects federal agencies and metropolitan planning organizations, which by definition are designated only for metropolitan areas with a population of at least 50,000. These organizations do not constitute small entities.

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.

D. Unfunded Mandates

Under Sections 202, 203, and 205 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must undertake various actions in association with proposed or final rules that include a federal mandate that may result in estimated costs of $100 million or more to the private sector, or to state, local, or tribal governments in the aggregate.

EPA has determined that to the extent this rule imposes any mandate within the meaning of the Unfunded Mandates Act, this final action does not include a mandate that may result in estimated costs of $100 million or more to state, local, or tribal governments in the aggregate or to the private sector. Therefore, EPA has not prepared a statement with respect to budgetary impacts.

List of Subjects

40 CFR Part 51

Environmental protection, Administrative practice and procedure, Carbon monoxide, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

40 CFR Part 93

Administrative practice and procedure, Air pollution control, Carbon monoxide, Intergovernmental relations, Ozone.

Dated: June 21, 1996.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble, 40 CFR parts 51 and 93 are proposed to be amended as follows:

PART 51—[AMENDED]

1. The authority citation for part 51 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

2. Subpart T is amended by removing §§ 51.392 through 51.464 and by revising § 51.390 to read as follows:

Subpart T—Conformity to State or Federal Implementation Plans of Transportation Plans, Programs, and Projects Developed, Funded or Approved Under Title 23 U.S.C. or the Federal Transit Laws

§ 51.390 Implementation plan revision.

(a) States with areas subject to this rule must submit to the EPA and DOT a revision to their implementation plan which contains criteria and procedures for DOT, MPOs and other State or local agencies to assess the conformity of transportation plans, programs, and projects, consistent with these regulations. This revision is to be submitted by November 25, 1994 (or within 12 months of an area's redesignation from attainment to nonattainment, if the State has not previously submitted such a revision). Further revisions to the implementation plan required by amendments to part 93, subpart A of this chapter must be submitted within 12 months of the date of publication of such final amendments. EPA will provide DOT with a 30-day comment period before taking action to approve or disapprove the submission. A State's conformity provisions may contain criteria and procedures more stringent than the requirements described in these regulations only if the State's conformity provisions apply equally to non-federal as well as Federal entities.

(b) The Federal conformity rules under this subpart and part 93 of this chapter, in addition to any existing applicable State requirements, establish the conformity criteria and procedures necessary to meet the requirements of Clean Air Act section 176(c) until such time as EPA approves the required conformity implementation plan revision. Following EPA approval of the State conformity provisions (or a portion thereof) in a revision to the applicable implementation plan, conformity determinations would be governed by the approved (or approved portion of the) State criteria and procedures. The Federal conformity regulations contained in part 93 of this chapter would apply only for the portion, if any, of the State's conformity provisions that is not approved by EPA. In addition, any previously applicable implementation plan conformity requirements remain enforceable until the State revises its applicable implementation plan to specifically remove them and that revision is approved by EPA.

(c) The implementation plan revision required by this section must meet all of the requirements of part 93, subpart A of this chapter.

(d) In order for EPA to approve the implementation plan revision submitted to EPA and DOT under this section, the plan must address all requirements of this subpart in a manner which gives them full legal effect. In particular, the revision shall incorporate the provisions of the following sections of this subpart in verbatim form, except insofar as needed to clarify or to give effect to a

stated intent in the revision to establish criteria and procedures more stringent than the requirements stated in these sections of this chapter: §§ 93.101, 93.102, 93.103, 93.104, 93.106, 93.109, 93.110, 93.111, 93.112, 93.113, 93.114, 93.115, 93.116, 93.117, 93.118, 93.119, 93.120, 93.121, 93.126, and 93.127 of this chapter.

PART 93—[AMENDED]

3. The authority citation for part 93 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

4. Subpart A is revised to read as follows:

Subpart A—Conformity to State or Federal Implementation Plans of Transportation Plans, Programs, and Projects Developed, Funded or Approved Under Title 23 U.S.C. or the Federal Transit Laws

Sec.

§ 93.100 Purpose.

The purpose of this subpart is to implement § 176(c) of the Clean Air Act (CAA), as amended (42 U.S.C. 7401 et seq.), and the related requirements of 23 U.S.C. 109(j), with respect to the conformity of transportation plans, programs, and projects which are developed, funded, or approved by the United States Department of Transportation (DOT), and by metropolitan planning organizations (MPOs) or other recipients of funds under title 23 U.S.C. or the Federal Transit Laws (49 U.S.C. Chapter 53). This subpart sets forth policy, criteria, and procedures for demonstrating and assuring conformity of such activities to an applicable implementation plan developed pursuant to section 110 and Part D of the CAA.

§ 93.101 Definitions.

Terms used but not defined in this subpart shall have the meaning given them by the CAA, titles 23 and 49 U.S.C., other Environmental Protection Agency (EPA) regulations, or other DOT regulations, in that order of priority.

Applicable implementation plan is defined in section 302(q) of the CAA and means the portion (or portions) of the implementation plan, or most recent revision thereof, which has been approved under section 110, or promulgated under section 110(c), or promulgated or approved pursuant to regulations promulgated under section 301(d) and which implements the relevant requirements of the CAA.

CAA means the Clean Air Act, as amended.

Cause or contribute to a new violation for a project means:

(1) To cause or contribute to a new violation of a standard in the area substantially affected by the project or over a region which would otherwise not be in violation of the standard during the future period in question, if the project were not implemented, or

(2) To contribute to a new violation in a manner that would increase the frequency or severity of a new violation of a standard in such area.

Clean data means air quality monitoring data determined by EPA to meet the requirements of 40 CFR part 58 that indicate attainment of the national ambient air quality standard.

Control strategy implementation plan revision is the implementation plan which contains specific strategies for controlling the emissions of and reducing ambient levels of pollutants in order to satisfy CAA requirements for demonstrations of reasonable further progress and attainment (CAA sections 182(b)(1), 182(c)(2)(A), 182(c)(2)(B), 187(a)(7), 189(a)(1)(B), and 189(b)(1)(A); and sections 192(a) and 192(b), for nitrogen dioxide).

Design concept means the type of facility identified by the project, e.g., freeway, expressway, arterial highway, grade-separated highway, reserved right-of-way rail transit, mixed-traffic rail transit, exclusive busway, etc.

Design scope means the design aspects which will affect the proposed facility's impact on regional emissions, usually as they relate to vehicle or person carrying capacity and control, e.g., number of lanes or tracks to be constructed or added, length of project, signalization, access control including approximate number and location of interchanges, preferential treatment for high-occupancy vehicles, etc.

DOT means the United States Department of Transportation.

EPA means the Environmental Protection Agency.

FHWA means the Federal Highway Administration of DOT.

FHWA/FTA project, for the purpose of this subpart, is any highway or transit project which is proposed to receive funding assistance and approval through the Federal-Aid Highway program or the Federal mass transit program, or requires Federal Highway Administration (FHWA) or Federal Transit Administration (FTA) approval for some aspect of the project, such as connection to an interstate highway or deviation from applicable design standards on the interstate system.

FTA means the Federal Transit Administration of DOT.

Forecast period with respect to a transportation plan is the period covered by the transportation plan pursuant to 23 CFR part 450.

Highway project is an undertaking to implement or modify a highway facility or highway-related program. Such an undertaking consists of all required phases necessary for implementation. For analytical purposes, it must be defined sufficiently to:

(1) Connect logical termini and be of sufficient length to address environmental matters on a broad scope;

(2) Have independent utility or significance, i.e., be usable and be a reasonable expenditure even if no

additional transportation improvements in the area are made; and

(3) Not restrict consideration of alternatives for other reasonably foreseeable transportation improvements.

Horizon year is a year for which the transportation plan describes the envisioned transportation system according to § 93.106 of this subpart.

Hot-spot analysis is an estimation of likely future localized CO and PM_{10} pollutant concentrations and a comparison of those concentrations to the national ambient air quality standards. Hot-spot analysis assesses impacts on a scale smaller than the entire nonattainment or maintenance area, including, for example, congested roadway intersections and highways or transit terminals, and uses an air quality dispersion model to determine the effects of emissions on air quality.

Increase the frequency or severity means to cause a location or region to exceed a standard more often or to cause a violation at a greater concentration than previously existed and/or would otherwise exist during the future period in question, if the project were not implemented.

ISTEA means the Intermodal Surface Transportation Efficiency Act of 1991.

Maintenance area means any geographic region of the United States previously designated nonattainment pursuant to the CAA Amendments of 1990 and subsequently redesignated to attainment subject to the requirement to develop a maintenance plan under section 175A of the CAA, as amended.

Maintenance plan means an implementation plan under section 175A of the CAA, as amended.

Metropolitan planning organization (MPO) is that organization designated as being responsible, together with the State, for conducting the continuing, cooperative, and comprehensive planning process under 23 U.S.C. 134 and 49 U.S.C. 1607. It is the forum for cooperative transportation decision-making.

Milestone has the meaning given in sections 182(g)(1) and 189(c) of the CAA. A milestone consists of an emissions level and the date on which it is required to be achieved.

Motor vehicle emissions budget is that portion of the total allowable emissions defined in the submitted or approved control strategy implementation plan revision or maintenance plan for a certain date for the purpose of meeting reasonable further progress milestones or demonstrating attainment or maintenance of the NAAQS, for any criteria pollutant or its precursors, allocated to highway and transit vehicle use and emissions.

National ambient air quality standards (NAAQS) are those standards established pursuant to section 109 of the CAA.

NEPA means the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 et seq.).

NEPA process completion, for the purposes of this subpart, with respect to FHWA or FTA, means the point at which there is a specific action to make a determination that a project is categorically excluded, to make a Finding of No Significant Impact, or to issue a record of decision on a Final Environmental Impact Statement under NEPA.

Nonattainment area means any geographic region of the United States which has been designated as nonattainment under § 107 of the CAA for any pollutant for which a national ambient air quality standard exists.

Project means a highway project or transit project.

Protective finding means a determination by EPA that the control strategy contained in a submitted control strategy implementation plan revision would have been considered approvable with respect to requirements for emissions reductions if all committed measures had been submitted in enforceable form as required by Clean Air Act section 110 (a)(2)(A).

Recipient of funds designated under title 23 U.S.C. or the Federal Transit Laws means any agency at any level of State, county, city, or regional government that routinely receives title 23 U.S.C. or Federal Transit Laws funds to construct FHWA/FTA projects, operate FHWA/FTA projects or equipment, purchase equipment, or undertake other services or operations via contracts or agreements. This definition does not include private landowners or developers, or contractors or entities that are only paid for services or products created by their own employees.

Regionally significant project means a transportation project (other than an exempt project) that is on a facility which serves regional transportation needs (such as access to and from the area outside of the region, major activity centers in the region, major planned developments such as new retail malls, sports complexes, etc., or transportation terminals as well as most terminals themselves) and would normally be included in the modeling of a metropolitan area's transportation network, including at a minimum all principal arterial highways and all fixed guideway transit facilities that offer an alternative to regional highway travel.

Standard means a national ambient air quality standard.

Transit is mass transportation by bus, rail, or other conveyance which provides general or special service to the public on a regular and continuing basis. It does not include school buses or charter or sightseeing services.

Transit project is an undertaking to implement or modify a transit facility or transit-related program; purchase transit vehicles or equipment; or provide financial assistance for transit operations. It does not include actions that are solely within the jurisdiction of local transit agencies, such as changes in routes, schedules, or fares. It may consist of several phases. For analytical purposes, it must be defined inclusively enough to:

(1) Connect logical termini and be of sufficient length to address environmental matters on a broad scope;

(2) Have independent utility or independent significance, i.e., be a reasonable expenditure even if no additional transportation improvements in the area are made; and

(3) Not restrict consideration of alternatives for other reasonably foreseeable transportation improvements.

Transportation control measure (TCM) is any measure that is specifically identified and committed to in the applicable implementation plan that is either one of the types listed in section 108 of the CAA, or any other measure for the purpose of reducing emissions or concentrations of air pollutants from transportation sources by reducing vehicle use or changing traffic flow or congestion conditions. Notwithstanding the above, vehicle technology-based, fuel-based, and maintenance-based measures which control the emissions from vehicles under fixed traffic conditions are not TCMs for the purposes of this subpart.

Transportation improvement program (TIP) means a staged, multiyear, intermodal program of transportation projects covering a metropolitan planning area which is consistent with the metropolitan transportation plan, and developed pursuant to 23 CFR part 450.

Transportation plan means the official intermodal metropolitan transportation plan that is developed through the metropolitan planning process for the metropolitan planning area, developed pursuant to 23 CFR part 450.

Transportation project is a highway project or a transit project.

§ 93.102 Applicability.

(a) *Action applicability.* (1) Except as provided for in paragraph (c) of this section or § 93.126, conformity determinations are required for:

(i) The adoption, acceptance, approval or support of transportation plans and transportation plan amendments developed pursuant to 23 CFR part 450 or 49 CFR part 613 by an MPO or DOT;

(ii) The adoption, acceptance, approval or support of TIPs and TIP amendments developed pursuant to 23 CFR part 450 or 49 CFR part 613 by an MPO or DOT; and

(iii) The approval, funding, or implementation of FHWA/FTA projects.

(2) Conformity determinations are not required under this rule for individual projects which are not FHWA/FTA projects. However, § 93.121 applies to such projects if they are regionally significant.

(b) *Geographic Applicability.* The provisions of this subpart shall apply in all nonattainment and maintenance areas for transportation-related criteria pollutants for which the area is designated nonattainment or has a maintenance plan.

(1) The provisions of this subpart apply with respect to emissions of the following criteria pollutants: Ozone, carbon monoxide (CO), nitrogen dioxide (NO_2), and particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers (PM_{10}).

(2) The provisions of this subpart apply with respect to emissions of the following precursor pollutants:

(i) Volatile organic compounds (VOC) and nitrogen oxides (NO_X) in ozone areas;

(ii) NO_X in NO_2 areas; and

(iii) VOC, NO_X, and PM_{10} in PM_{10} areas if the EPA Regional Administrator or the director of the State air agency has made a finding that transportation-related precursor emissions within the nonattainment area are a significant contributor to the PM_{10} nonattainment problem and has so notified the MPO and DOT, or if the applicable implementation plan (or implementation plan submission) establishes a budget for such emissions as part of the reasonable further progress, attainment or maintenance strategy.

(3) The provisions of this subpart apply to maintenance areas for 20 years from the date EPA approves the area's request under section 107(d) of the CAA for redesignation to attainment, unless the applicable implementation plan specifies that the provisions of this subpart shall apply for more than 20 years.

(c) Limitations. (1) Projects subject to this regulation for which the NEPA process and a conformity determination have been completed by DOT may proceed toward implementation without further conformity determinations unless more than three years have elapsed since the most recent major step (NEPA process completion; start of final design; acquisition of a significant portion of the right-of-way; or approval of the plans, specifications and estimates) occurred. All phases of such projects which were considered in the conformity determination are also included, if those phases were for the purpose of funding, final design, right-of-way acquisition, construction, or any combination of these phases.

(2) A new conformity determination for the project will be required if there is a significant change in project design concept and scope, if a supplemental environmental document for air quality purposes is initiated, or if three years have elapsed since the most recent major step to advance the project occurred.

(d) *Grace period for new nonattainment areas.* For areas or portions of areas which have been designated attainment for either ozone, CO, PM_{10} or NO_2 since 1990 and are subsequently redesignated to nonattainment for any of these pollutants, the provisions of this subpart shall not apply for 12 months following the date of final designation to nonattainment for such pollutant.

§ 93.103 Priority.

When assisting or approving any action with air quality-related consequences, FHWA and FTA shall give priority to the implementation of those transportation portions of an applicable implementation plan prepared to attain and maintain the NAAQS. This priority shall be consistent with statutory requirements for allocation of funds among States or other jurisdictions.

§ 93.104 Frequency of conformity determinations.

(a) Conformity determinations and conformity redeterminations for transportation plans, TIPs, and FHWA/FTA projects must be made according to the requirements of this section and the applicable implementation plan.

(b) Frequency of conformity determinations for transportation plans.

(1) Each new transportation plan must be demonstrated to conform before the transportation plan is approved by the MPO or accepted by DOT.

(2) All transportation plan revisions must be found to conform before the transportation plan revisions are approved by the MPO or accepted by DOT, unless the revision merely adds or deletes exempt projects listed in § 93.126 or § 93.127. The conformity determination must be based on the transportation plan and the revision taken as a whole.

(3) The MPO and DOT must determine the conformity of the transportation plan no less frequently than every three years. If more than three years elapse after DOT's conformity determination without the MPO and DOT determining conformity of the transportation plan, the existing conformity determination will lapse.

(c) Frequency of conformity determinations for transportation improvement programs.

(1) A new TIP must be demonstrated to conform before the TIP is approved by the MPO or accepted by DOT.

(2) A TIP amendment requires a new conformity determination for the entire TIP before the amendment is approved by the MPO or accepted by DOT, unless the amendment merely adds or deletes exempt projects listed in § 93.126 or § 93.127.

(3) The MPO and DOT must determine the conformity of the TIP no less frequently than every three years. If more than three years elapse after DOT's conformity determination without the MPO and DOT determining conformity of the TIP, the existing conformity determination will lapse.

(4) After an MPO adopts a new or revised transportation plan, conformity of the TIP must be redetermined by the MPO and DOT within six months from the date of DOT's conformity determination for the transportation plan, unless the new or revised plan merely adds or deletes exempt projects listed in §§ 93.126 and 93.127. Otherwise, the existing conformity determination for the TIP will lapse.

(d) Projects. FHWA/FTA projects must be found to conform before they are adopted, accepted, approved, or funded. Conformity must be redetermined for any FHWA/FTA project if three years have elapsed since the most recent major step to advance the project (NEPA process completion; start of final design; acquisition of a significant portion of the right-of-way; or approval of the plans, specifications and estimates) occurred.

(e) Triggers for transportation plan and TIP conformity determinations. Conformity of existing transportation plans and TIPs must be redetermined within 18 months of the following, or the existing conformity determination will lapse, and no new project-level conformity determinations may be made

until conformity of the transportation plan and TIP has been determined by the MPO and DOT:

(1) November 24, 1993;

(2) The date of the State's initial submission to EPA of each control strategy implementation plan or maintenance plan establishing a motor vehicle emissions budget;

(3) EPA approval of a control strategy implementation plan revision or maintenance plan which establishes or revises a motor vehicle emissions budget;

(4) EPA approval of an implementation plan revision that adds, deletes, or changes TCMs; and

(5) EPA promulgation of an implementation plan which establishes or revises a motor vehicle emissions budget or adds, deletes, or changes TCMs.

§ 93.105 Consultation.

(a) *General.* The implementation plan revision required under § 51.390 of this chapter shall include procedures for interagency consultation (Federal, State, and local) and resolution of conflicts.

(1) The implementation plan revision shall include procedures to be undertaken by MPOs, State departments of transportation, and DOT with State and local air quality agencies and EPA before making conformity determinations, and by State and local air agencies and EPA with MPOs, State departments of transportation, and DOT in developing applicable implementation plans.

(2) Before EPA approves the conformity implementation plan revision required by § 51.390 of this chapter, MPOs and State departments of transportation must provide reasonable opportunity for consultation with State air agencies, local air quality and transportation agencies, DOT, and EPA, including consultation on the issues described in paragraph (c)(1) of this section, before making conformity determinations.

(b) *Interagency consultation procedures: General factors.* (1) States shall provide well-defined consultation procedures in the implementation plan whereby representatives of the MPOs, State and local air quality planning agencies, State and local transportation agencies, and other organizations with responsibilities for developing, submitting, or implementing provisions of an implementation plan required by the CAA must consult with each other and with local or regional offices of EPA, FHWA, and FTA on the development of the implementation plan, the transportation plan, the TIP, and associated conformity determinations.

(2) Interagency consultation procedures shall include at a minimum the general factors listed below and the specific processes in paragraph (c) of this section:

(i) The roles and responsibilities assigned to each agency at each stage in the implementation plan development process and the transportation planning process, including technical meetings;

(ii) The organizational level of regular consultation;

(iii) A process for circulating (or providing ready access to) draft documents and supporting materials for comment before formal adoption or publication;

(iv) The frequency of, or process for convening, consultation meetings and responsibilities for establishing meeting agendas;

(v) A process for responding to the significant comments of involved agencies; and

(vi) A process for the development of a list of the TCMs which are in the applicable implementation plan.

(c) *Interagency consultation procedures: Specific processes.* Interagency consultation procedures shall also include the following specific processes:

(1) A process involving the MPO, State and local air quality planning agencies, State and local transportation agencies, EPA, and DOT for the following:

(i) Evaluating and choosing a model (or models) and associated methods and assumptions to be used in hot-spot analyses and regional emissions analyses;

(ii) Determining which minor arterials and other transportation projects should be considered ''regionally significant'' for the purposes of regional emissions analysis (in addition to those functionally classified as principal arterial or higher or fixed guideway systems or extensions that offer an alternative to regional highway travel), and which projects should be considered to have a significant change in design concept and scope from the transportation plan or TIP;

(iii) Evaluating whether projects otherwise exempted from meeting the requirements of this subpart (see §§ 93.126 and 93.127) should be treated as non-exempt in cases where potential adverse emissions impacts may exist for any reason;

(iv) Making a determination, as required by § 93.113(c)(1), whether past obstacles to implementation of TCMs which are behind the schedule established in the applicable implementation plan have been identified and are being overcome, and whether State and local agencies with influence over approvals or funding for TCMs are giving maximum priority to approval or funding for TCMs. This process shall also consider whether delays in TCM implementation necessitate revisions to the applicable implementation plan to remove TCMs or substitute TCMs or other emission reduction measures;

(v) Identifying, as required by § 93.123(d), projects located at sites in PM_{10} nonattainment areas which have vehicle and roadway emission and dispersion characteristics which are essentially identical to those at sites which have violations verified by monitoring, and therefore require quantitative PM_{10} hot-spot analysis; and

(vi) Notification of transportation plan or TIP revisions or amendments which merely add or delete exempt projects listed in § 93.126.

(2) A process involving the MPO and State and local air quality planning agencies and transportation agencies for the following:

(i) Evaluating events which will trigger new conformity determinations in addition to those triggering events established in § 93.104; and

(ii) Consulting on emissions analysis for transportation activities which cross the borders of MPOs or nonattainment areas or air basins.

(3) Where the metropolitan planning area does not include the entire nonattainment or maintenance area, a process involving the MPO and the State department of transportation for cooperative planning and analysis for purposes of determining conformity of all projects outside the metropolitan area and within the nonattainment or maintenance area.

(4) A process to ensure that plans for construction of regionally significant projects which are not FHWA/FTA projects (including projects for which alternative locations, design concept and scope, or the no-build option are still being considered), including those by recipients of funds designated under title 23 U.S.C. or the Federal Transit Laws, are disclosed to the MPO on a regular basis, and to ensure that any changes to those plans are immediately disclosed;

(5) A process involving the MPO and other recipients of funds designated under title 23 U.S.C. or the Federal Transit Laws for assuming the location and design concept and scope of projects which are disclosed to the MPO as required by paragraph (c)(4) of this section but whose sponsors have not yet decided these features, in sufficient

detail to perform the regional emissions analysis according to the requirements of § 93.122.

(6) A process for consulting on the design, schedule, and funding of research and data collection efforts and regional transportation model development by the MPO (e.g., household/travel transportation surveys).

(7) A process for providing final documents (including applicable implementation plans and implementation plan revisions) and supporting information to each agency after approval or adoption. This process is applicable to all agencies described in paragraph (a)(1) of this section, including Federal agencies.

(d) *Resolving conflicts.* Conflicts among State agencies or between State agencies and an MPO shall be escalated to the Governor if they cannot be resolved by the heads of the involved agencies. The State air agency has 14 calendar days to appeal to the Governor after the State DOT or MPO has notified the State air agency head of the resolution of his or her comments. The implementation plan revision required by § 51.390 of this chapter shall define the procedures for starting the 14-day clock. If the State air agency appeals to the Governor, the final conformity determination must have the concurrence of the Governor. If the State air agency does not appeal to the Governor within 14 days, the MPO or State department of transportation may proceed with the final conformity determination. The Governor may delegate his or her role in this process, but not to the head or staff of the State or local air agency, State department of transportation, State transportation commission or board, or an MPO.

(e) *Public consultation procedures.* Affected agencies making conformity determinations on transportation plans, programs, and projects shall establish a proactive public involvement process which provides opportunity for public review and comment by, at a minimum, providing reasonable public access to technical and policy information considered by the agency at the beginning of the public comment period and prior to taking formal action on a conformity determination for all transportation plans and TIPs, consistent with these requirements and those of 23 CFR 450.316(b). Any charges imposed for public inspection and copying should be consistent with the fee schedule contained in 49 CFR 7.95. In addition, these agencies must specifically address in writing all public comments that known plans for a regionally significant project which is not receiving FHWA or FTA funding or approval have not been properly reflected in the emissions analysis supporting a proposed conformity finding for a transportation plan or TIP. These agencies shall also provide opportunity for public involvement in conformity determinations for projects where otherwise required by law.

§ 93.106 Content of transportation plans.

(a) *Transportation plans adopted after January 1, 1997 in serious, severe, or extreme ozone nonattainment areas and in serious CO nonattainment areas.* If the metropolitan planning area contains an urbanized area population greater than 200,000, the transportation plan must specifically describe the transportation system envisioned for certain future years which shall be called horizon years.

(1) The agency or organization developing the transportation plan may choose any years to be horizon years, subject to the following restrictions:

(i) Horizon years may be no more than 10 years apart.

(ii) The first horizon year may be no more than 10 years from the base year used to validate the transportation demand planning model.

(iii) If the attainment year is in the time span of the transportation plan, the attainment year must be a horizon year.

(iv) The last horizon year must be the last year of the transportation plan's forecast period.

(2) For these horizon years:

(i) The transportation plan shall quantify and document the demographic and employment factors influencing expected transportation demand, including land use forecasts, in accordance with implementation plan provisions and the consultation requirements specified by § 93.105;

(ii) The highway and transit system shall be described in terms of the regionally significant additions or modifications to the existing transportation network which the transportation plan envisions to be operational in the horizon years. Additions and modifications to the highway network shall be sufficiently identified to indicate intersections with existing regionally significant facilities, and to determine their effect on route options between transportation analysis zones. Each added or modified highway segment shall also be sufficiently identified in terms of its design concept and design scope to allow modeling of travel times under various traffic volumes, consistent with the modeling methods for area-wide transportation analysis in use by the MPO. Transit facilities, equipment, and services envisioned for the future shall be identified in terms of design concept, design scope, and operating policies that are sufficient for modeling of their transit ridership. Additions and modifications to the transportation network shall be described sufficiently to show that there is a reasonable relationship between expected land use and the envisioned transportation system; and

(iii) Other future transportation policies, requirements, services, and activities, including intermodal activities, shall be described.

(b) *Moderate areas reclassified to serious* Ozone or CO nonattainment areas which are reclassified from moderate to serious must meet the requirements of paragraph (a) of this section within two years from the date of reclassification.

(c) *Transportation plans for other areas* Transportation plans for other areas must meet the requirements of paragraph (a) of this section at least to the extent it has been the previous practice of the MPO to prepare plans which meet those requirements. Otherwise, the transportation system envisioned for the future must be sufficiently described within the transportation plans so that a conformity determination can be made according to the criteria and procedures of §§ 93.109—93.119.

(d) *Savings* The requirements of this section supplement other requirements of applicable law or regulation governing the format or content of transportation plans.

§ 93.107 Relationship of transportation plan and TIP conformity with the NEPA process.

The degree of specificity required in the transportation plan and the specific travel network assumed for air quality modeling do not preclude the consideration of alternatives in the NEPA process or other project development studies. Should the NEPA process result in a project with design concept and scope significantly different from that in the transportation plan or TIP, the project must meet the criteria in §§ 93.109—93.119 for projects not from a TIP before NEPA process completion.

§ 93.108 Fiscal constraints for transportation plans and TIPs.

Transportation plans and TIPs must be fiscally constrained consistent with DOT's metropolitan planning regulations at 23 CFR part 450 in order to be found in conformity.

§ 93.109 Criteria and procedures for determining conformity of transportation plans, programs, and projects: General.

(a) In order for each transportation plan, program, and FHWA/FTA project to be found to conform, the MPO and DOT must demonstrate that the applicable criteria and procedures in this subpart are satisfied, and the MPO and DOT must comply with all applicable conformity requirements of implementation plans and of court orders for the area which pertain specifically to conformity. The criteria for making conformity determinations differ based on the action under review (transportation plans, TIPs, and FHWA/FTA projects), the relevant pollutant(s), and the status of the implementation plan.

(b) The following table indicates the criteria and procedures in §§ 93.110–93.119 which apply for transportation plans, TIPs, and FHWA/FTA projects. Paragraphs (c) through (f) of this section explain when the budget, emission reduction, and hot spot tests are required for each pollutant. Paragraph (g) of this section addresses isolated rural nonattainment and maintenance areas.

TABLE 1.—CONFORMITY CRITERIA

All Actions at All Times	
§ 93.110	Latest planning assumptions.
§ 93.111	Latest emissions model.
§ 93.112	Consultation.
Transportation Plan	
§ 93.113(b)	TCMs.
§ 93.118 OR § 93.119.	Emissions budget OR Emission reduction.
TIP	
§ 93.113(c)	TCMs.
§ 93.118 OR § 93.119.	Emissions budget OR Emission reduction.
Project (From a Conforming Plan and TIP)	
§ 93.114	Currently conforming plan and TIP.
§ 93.115	Project from a conforming plan and TIP.
§ 93.116	CO and PM_{10} hot spots.
§ 93.117	PM_{10} control measures.
Project (Not From a Conforming Plan and TIP)	
§ 93.113(d)	TCMs.
§ 93.114	Currently conforming plan and TIP.
§ 93.116	CO and PM_{10} hot spots.
§ 93.117	PM_{10} control measures.
§ 93.118 OR § 93.119.	Emissions budget OR Emission reduction.

(c) *Ozone nonattainment and maintenance areas.* In addition to the criteria listed in Table 1 that are required to be satisfied at all times, in ozone nonattainment and maintenance areas conformity determinations must include a demonstration that the budget and/or emission reduction tests are satisfied as described in the following paragraphs.

(1) In ozone areas the budget test must be satisfied as required by § 93.118 for conformity determinations made:

(i) 45 days after a control strategy implementation plan revision or maintenance plan has been submitted to EPA, unless EPA has declared the motor vehicle emissions budget inadequate for transportation conformity purposes; or

(ii) After EPA has declared that the motor vehicle emissions budget in a submitted control strategy implementation plan revision or maintenance plan is adequate for transportation conformity purposes.

(2) In moderate and above ozone nonattainment areas the emission reduction tests must be satisfied as required by § 93.119 for conformity determinations made:

(i) During the first 45 days after a control strategy implementation plan revision or maintenance plan has been submitted to EPA, unless EPA has declared a motor vehicle emissions budget adequate for transportation conformity purposes; or

(ii) If EPA has declared the motor vehicle emissions budget in a submitted control strategy implementation plan revision or maintenance plan inadequate for transportation conformity purposes, and there is no previously established motor vehicle emissions budget in the approved SIP or a previously submitted control strategy implementation plan revision or maintenance plan.

(3) An ozone nonattainment area must satisfy the emission reduction test for NO_X, as required by § 93.119, if the implementation plan or plan submission that is applicable for the purposes of conformity determinations is a 15% SIP or Phase I attainment demonstration that does not include a motor vehicle emissions budget for NO_X. The implementation plan will be considered to establish a motor vehicle emissions budget for NO_X if the implementation plan or plan submission contains an explicit NO_X motor vehicle emissions budget that is intended to act as a ceiling on future NO_X emissions, and the NO_X motor vehicle emissions budget is a net reduction from NO_X emissions levels in 1990.

(4) Marginal and below ozone nonattainment areas that have three consecutive years of clean data and that have not submitted a maintenance plan must satisfy one of the following requirements:

(i) The emission reduction tests as required by § 93.119;

(ii) The State air quality agency shall determine (subject to the interagency consultation process required by § 93.105) the motor vehicle emissions of ozone precursors in the most recent year of clean data. The budget test required by § 93.118 must be satisfied, with these motor vehicle emission levels serving as the motor vehicle emissions budget; or

(iii) The State shall submit to EPA an implementation plan revision that contains motor vehicle emissions budget(s) and an attainment or maintenance demonstration, and the budget test required by § 93.118 must be satisfied using the submitted motor vehicle emissions budget(s) (as described in paragraph (c)(1) of this section).

(5) Marginal and below ozone nonattainment areas that do not have three consecutive years of clean data must satisfy one of the following requirements:

(i) The emission reduction tests required by § 93.119; or

(ii) The State shall submit to EPA an implementation plan revision that contains motor vehicle emissions budget(s) and an attainment demonstration, and the budget test required by § 93.118 must be satisfied using the submitted motor vehicle emissions budget(s) (as described in paragraph (c)(1) of this section).

(6) Notwithstanding paragraphs (c)(1) and (c)(2) of this section, moderate and above ozone nonattainment areas with three years of clean data that have not submitted a maintenance plan and that EPA has determined are not subject to the Clean Air Act reasonable further progress and attainment demonstration requirements must satisfy one of the following requirements:

(i) The emission reduction tests as required by § 93.119;

(ii) The budget test as required by § 93.118, using the motor vehicle emissions budgets in the submitted control strategy implementation plan (subject to the timing requirements of paragraph (c)(1) of this section); or

(iii) The State air quality agency shall determine (subject to the interagency consultation process required by

§ 93.105) the motor vehicle emissions of ozone precursors in the most recent year of clean data. The budget test required by § 93.118 must be satisfied, with these motor vehicle emission levels serving as the motor vehicle emissions budget.

(d) *CO nonattainment and maintenance areas.* In addition to the criteria listed in Table 1 that are required to be satisfied at all times, in CO nonattainment and maintenance areas conformity determinations must include a demonstration that the hot spot, budget and/or emission reduction tests are satisfied as described in the following paragraphs.

(1) FHWA/FTA projects in CO nonattainment or maintenance areas must satisfy the hot spot test required by § 93.116 at all times. Until a CO attainment demonstration or maintenance plan is approved by EPA, FHWA/FTA projects must also satisfy the hot spot test required by § 93.116(b).

(2) In CO areas the budget test must be satisfied as required by § 93.118 for conformity determinations made:

(i) 45 days after a control strategy implementation plan revision or maintenance plan has been submitted to EPA, unless EPA has declared the motor vehicle emissions budget inadequate for transportation conformity purposes; or

(ii) After EPA has declared that the motor vehicle emissions budget in a submitted control strategy implementation plan revision or maintenance plan is adequate for transportation conformity purposes.

(3) In moderate CO nonattainment areas with a design value greater than 12.7 ppm and serious CO nonattainment areas the emission reduction tests must be satisfied as required by § 93.119 for conformity determinations made:

(i) During the first 45 days after a control strategy implementation plan revision or maintenance plan has been submitted to EPA, unless EPA has declared a motor vehicle emissions budget adequate for transportation conformity purposes; or

(ii) If EPA has declared the motor vehicle emissions budget in a submitted control strategy implementation plan revision or maintenance plan inadequate for transportation conformity purposes, and there is no previously established motor vehicle emissions budget in the approved SIP or a previously submitted control strategy implementation plan revision or maintenance plan.

(4) If a moderate CO nonattainment area with a design value of 12.7 ppm or less or a not classified CO nonattainment area has two consecutive years of clean data and has not submitted a maintenance plan, one of the following requirements must be satisfied:

(i) The emission reduction tests as required by § 93.119;

(ii) The State air quality agency shall determine (subject to the interagency consultation process required by § 93.105) the motor vehicle emissions of CO in the most recent year of clean data. The budget test required by § 93.118 must be satisfied, with these motor vehicle emission levels serving as the motor vehicle emissions budget; or

(iii) The State shall submit to EPA an implementation plan revision that contains motor vehicle emissions budget(s) and an attainment or maintenance demonstration, and the budget test required by § 93.118 must be satisfied using the submitted motor vehicle emissions budget(s) (as described in paragraph (d)(1) of this section).

(5) If a moderate CO nonattainment area with a design value of 12.7 ppm or less or a not classified CO nonattainment area does not have two consecutive years of clean data, one of the following requirements must be satisfied:

(i) The emission reduction tests required by § 93.119; or

(ii) The State shall submit to EPA an implementation plan revision that contains motor vehicle emissions budget(s) and an attainment demonstration, and the budget test required by § 93.118 must be satisfied using the submitted motor vehicle emissions budget(s) (as described in paragraph (d)(1) of this section).

(e) *PM_{10} nonattainment and maintenance areas.* In addition to the criteria listed in Table 1 that are required to be satisfied at all times, in PM_{10} nonattainment and maintenance areas conformity determinations must include a demonstration that the hot spot, budget and/or emission reduction tests are satisfied as described in the following paragraphs.

(1) FHWA/FTA projects in PM_{10} nonattainment or maintenance areas must satisfy the hot spot test required by § 93.116.

(2) In PM_{10} areas the budget test must be satisfied as required by § 93.118 for conformity determinations made:

(i) 45 days after a control strategy implementation plan revision or maintenance plan has been submitted to EPA, unless EPA has declared the motor vehicle emissions budget inadequate for transportation conformity purposes; or

(ii) After EPA has declared that the motor vehicle emissions budget in a submitted control strategy implementation plan revision or maintenance plan is adequate for transportation conformity purposes.

(3) In PM_{10} nonattainment areas the emission reduction tests must be satisfied as required by § 93.119 for conformity determinations made:

(i) During the first 45 days after a control strategy implementation plan revision or maintenance plan has been submitted to EPA, unless EPA has declared a motor vehicle emissions budget adequate for transportation conformity purposes;

(ii) If EPA has declared the motor vehicle emissions budget in a submitted control strategy implementation plan revision or maintenance plan inadequate for transportation conformity purposes, and there is no previously established motor vehicle emissions budget in the approved SIP or a previously submitted control strategy implementation plan revision or maintenance plan; or

(iii) The submitted implementation plan revision is a demonstration of impracticability under CAA section 189(a)(1)(B)(ii) and does not demonstrate attainment.

(f) *NO_2 nonattainment and maintenance areas.* In addition to the criteria listed in Table 1 that are required to be satisfied at all times, in NO_2 nonattainment and maintenance areas conformity determinations must include a demonstration that the budget and/or emission reduction tests are satisfied as described in the following paragraphs.

(1) In NO_2 areas the budget test must be satisfied as required by § 93.118 for conformity determinations made:

(i) 45 days after a control strategy implementation plan revision or maintenance plan has been submitted to EPA, unless EPA has declared the motor vehicle emissions budget inadequate for transportation conformity purposes; or

(ii) After EPA has declared that the motor vehicle emissions budget in a submitted control strategy implementation plan revision or maintenance plan is adequate for transportation conformity purposes.

(2) In NO_2 areas the emission reduction tests must be satisfied as required by § 93.119 for conformity determinations made:

(i) During the first 45 days after a control strategy implementation plan revision or maintenance plan has been submitted to EPA, unless EPA has declared a motor vehicle emissions budget adequate for transportation conformity purposes; or

(ii) If EPA has declared the motor vehicle emissions budget in a submitted control strategy implementation plan revision or maintenance plan

inadequate for transportation conformity purposes, and there is no previously established motor vehicle emissions budget in the approved SIP or a previously submitted control strategy implementation plan revision or maintenance plan.

(g) *Isolated rural nonattainment and maintenance areas.* This paragraph applies to any nonattainment or maintenance area (or portion thereof) which does not have a metropolitan transportation plan or TIP and whose projects are not part of the emissions analysis of any MPO's metropolitan transportation plan or TIP. This paragraph does not apply to ''donut'' areas which are outside the metropolitan planning boundary and inside the nonattainment/maintenance area boundary.

(1) FHWA/FTA projects in all isolated rural nonattainment and maintenance areas must satisfy the requirements of §§ 93.110, 93.111, 93.112, 93.113(d), 93.116, and 93.117. Until EPA approves the control strategy implementation plan or maintenance plan for a rural CO nonattainment or maintenance area, FHWA/FTA projects must also satisfy the requirements of § 93.116(b) (''Localized CO and PM_{10} violations (hot spots)'').

(2) Isolated rural nonattainment and maintenance areas are subject to the budget and/or emission reduction tests as described in paragraphs (c)–(f) of this section, with the following modifications:

(i) When the requirements of §§ 93.118 and 93.119 apply to isolated rural nonattainment and maintenance areas, references to ''transportation plan'' or ''TIP'' should be taken to mean those projects in the statewide transportation plan or statewide TIP which are in the rural nonattainment or maintenance area.

(ii) In isolated rural nonattainment and maintenance areas that are subject to § 93.118, FHWA/FTA projects must be consistent with motor vehicle emissions budget(s) for the years in the timeframe of the attainment demonstration or maintenance plan. For years after the attainment year (if a maintenance plan has not been submitted) or after the last year of the maintenance plan, FHWA/FTA projects must satisfy one of the following requirements:

(A) § 93.118;

(B) § 93.119 (Emission reductions in areas without motor vehicle emissions budgets); or

(C) Air quality dispersion modeling must demonstrate that the FHWA/FTA project, in combination with all other regionally significant projects expected in the area in the timeframe of the statewide transportation plan, will not cause or contribute to any new violation of any standard in any areas; increase the frequency or severity of any existing violation of any standard in any area; or delay timely attainment of any standard or any required interim emission reductions or other milestones in any area. Control measures assumed in the analysis must be enforceable.

(iii) The choice of requirements in paragraph (g)(2)(ii) of this section and the methodology used to meet the requirements of paragraph (g)(2)(ii)(C) of this section must be determined through the interagency consultation process required in § 93.105 through which the relevant recipients of title 23 U.S.C. or Federal Transit Laws funds, the local air quality agency, the State air quality agency, and the State DOT should reach consensus about the option and methodology selected. EPA and DOT must be consulted through this process as well. In the event of unresolved disputes, conflicts may be escalated to the Governor consistent with the procedure in § 93.105(d), which applies for any State air agency comments on a conformity determination.

§ 93.110 Criteria and procedures: Latest planning assumptions.

(a) The conformity determination, with respect to all other applicable criteria in §§ 93.111–93.119, must be based upon the most recent planning assumptions in force at the time of the conformity determination. The conformity determination must satisfy the requirements of paragraphs (b) through (f) of this section.

(b) Assumptions must be derived from the estimates of current and future population, employment, travel, and congestion most recently developed by the MPO or other agency authorized to make such estimates and approved by the MPO. The conformity determination must also be based on the latest assumptions about current and future background concentrations.

(c) The conformity determination for each transportation plan and TIP must discuss how transit operating policies (including fares and service levels) and assumed transit ridership have changed since the previous conformity determination.

(d) The conformity determination must include reasonable assumptions about transit service and increases in transit fares and road and bridge tolls over time.

(e) The conformity determination must use the latest existing information regarding the effectiveness of the TCMs and other implementation plan measures which have already been implemented.

(f) Key assumptions shall be specified and included in the draft documents and supporting materials used for the interagency and public consultation required by § 93.105.

§ 93.111 Criteria and procedures: Latest emissions model.

(a) The conformity determination must be based on the latest emission estimation model available. This criterion is satisfied if the most current version of the motor vehicle emissions model specified by EPA for use in the preparation or revision of implementation plans in that State or area is used for the conformity analysis. Where EMFAC is the motor vehicle emissions model used in preparing or revising the applicable implementation plan, new versions must be approved by EPA before they are used in the conformity analysis.

(b) EPA will consult with DOT to establish a grace period following the specification of any new model.

(1) The grace period will be no less than three months and no more than 24 months after notice of availability is published in the Federal Register.

(2) The length of the grace period will depend on the degree of change in the model and the scope of re-planning likely to be necessary by MPOs in order to assure conformity. If the grace period will be longer than three months, EPA will announce the appropriate grace period in the Federal Register.

(c) Transportation plan and TIP conformity analyses for which the emissions analysis was begun during the grace period or before the Federal Register notice of availability of the latest emission model may continue to use the previous version of the model. Conformity determinations for projects may also be based on the previous model if the analysis was begun during the grace period or before the Federal Register notice of availability, and if the final environmental document for the project is issued no more than three years after the issuance of the draft environmental document.

§ 93.112 Criteria and procedures: Consultation.

Conformity must be determined according to the consultation procedures in this rule and in the applicable implementation plan, and according to the public involvement procedures established in compliance with 23 CFR part 450. Until the implementation plan revision required by § 51.390 of this chapter is fully approved by EPA, the conformity

determination must be made according to § 93.105(a)(2) and § 93.105(e) and the requirements of 23 CFR part 450.

§ 93.113 Criteria and procedures: Timely implementation of TCMs.

(a) The transportation plan, TIP, or any FHWA/FTA project which is not from a conforming plan and TIP must provide for the timely implementation of TCMs from the applicable implementation plan.

(b) For transportation plans, this criterion is satisfied if the following two conditions are met:

(1) The transportation plan, in describing the envisioned future transportation system, provides for the timely completion or implementation of all TCMs in the applicable implementation plan which are eligible for funding under title 23 U.S.C. or the Federal Transit Laws, consistent with schedules included in the applicable implementation plan.

(2) Nothing in the transportation plan interferes with the implementation of any TCM in the applicable implementation plan.

(c) For TIPs, this criterion is satisfied if the following conditions are met:

(1) An examination of the specific steps and funding source(s) needed to fully implement each TCM indicates that TCMs which are eligible for funding under title 23 U.S.C. or the Federal Transit Laws are on or ahead of the schedule established in the applicable implementation plan, or, if such TCMs are behind the schedule established in the applicable implementation plan, the MPO and DOT have determined that past obstacles to implementation of the TCMs have been identified and have been or are being overcome, and that all State and local agencies with influence over approvals or funding for TCMs are giving maximum priority to approval or funding of TCMs over other projects within their control, including projects in locations outside the nonattainment or maintenance area.

(2) If TCMs in the applicable implementation plan have previously been programmed for Federal funding but the funds have not been obligated and the TCMs are behind the schedule in the implementation plan, then the TIP cannot be found to conform if the funds intended for those TCMs are reallocated to projects in the TIP other than TCMs, or if there are no other TCMs in the TIP, if the funds are reallocated to projects in the TIP other than projects which are eligible for Federal funding intended for air quality improvement projects, e.g., the Congestion Mitigation and Air Quality Improvement Program.

(3) Nothing in the TIP may interfere with the implementation of any TCM in the applicable implementation plan.

(d) For FHWA/FTA projects which are not from a conforming transportation plan and TIP, this criterion is satisfied if the project does not interfere with the implementation of any TCM in the applicable implementation plan.

§ 93.114 Criteria and procedures: Currently conforming transportation plan and TIP.

There must be a currently conforming transportation plan and currently conforming TIP at the time of project approval.

(a) Only one conforming transportation plan or TIP may exist in an area at any time; conformity determinations of a previous transportation plan or TIP expire once the current plan or TIP is found to conform by DOT. The conformity determination on a transportation plan or TIP will also lapse if conformity is not determined according to the frequency requirements specified in § 93.104.

(b) This criterion is not required to be satisfied at the time of project approval for a TCM specifically included in the applicable implementation plan, provided that all other relevant criteria of this subpart are satisfied.

§ 93.115 Criteria and procedures: Projects from a plan and TIP.

(a) The project must come from a conforming plan and program. If this criterion is not satisfied, the project must satisfy all criteria in Table 1 for a project not from a conforming transportation plan and TIP. A project is considered to be from a conforming transportation plan if it meets the requirements of paragraph (b) of this section and from a conforming program if it meets the requirements of paragraph (c) of this section. Special provisions for TCMs in an applicable implementation plan are provided in paragraph (d) of this section.

(b) A project is considered to be from a conforming transportation plan if one of the following conditions applies:

(1) For projects which are required to be identified in the transportation plan in order to satisfy § 93.106 (''Content of transportation plans''), the project is specifically included in the conforming transportation plan and the project's design concept and scope have not changed significantly from those which were described in the transportation plan, or in a manner which would significantly impact use of the facility; or

(2) For projects which are not required to be specifically identified in the transportation plan, the project is identified in the conforming transportation plan, or is consistent with the policies and purpose of the transportation plan and will not interfere with other projects specifically included in the transportation plan.

(c) A project is considered to be from a conforming program if the following conditions are met:

(1) The project is included in the conforming TIP and the design concept and scope of the project were adequate at the time of the TIP conformity determination to determine its contribution to the TIP's regional emissions, and the project design concept and scope have not changed significantly from those which were described in the TIP; and

(2) If the TIP describes a project design concept and scope which includes project-level emissions mitigation or control measures, written commitments to implement such measures must be obtained from the project sponsor and/or operator as required by § 93.125(a) in order for the project to be considered from a conforming program. Any change in these mitigation or control measures that would significantly reduce their effectiveness constitutes a change in the design concept and scope of the project.

(d) *TCMs.* This criterion is not required to be satisfied for TCMs specifically included in an applicable implementation plan.

§ 93.116 Criteria and procedures: Localized CO and PM_{10} violations (hot spots).

(a) This paragraph applies at all times. The FHWA/FTA project must not cause or contribute to any new localized CO or PM_{10} violations or increase the frequency or severity of any existing CO or PM_{10} violations in CO and PM_{10} nonattainment and maintenance areas. This criterion is satisfied if it is demonstrated that no new local violations will be created and the severity or number of existing violations will not be increased as a result of the project. The demonstration must be performed according to the consultation requirements of § 93.105(c)(1)(i) and the methodology requirements of § 93.123.

(b) This paragraph applies for CO nonattainment areas as described in § 93.109(d)(1). Each FHWA/FTA project must eliminate or reduce the severity and number of localized CO violations in the area substantially affected by the project (in CO nonattainment areas).

This criterion is satisfied with respect to existing localized CO violations if it is demonstrated that existing localized CO violations will be eliminated or reduced in severity and number as a result of the project. The demonstration must be performed according to the consultation requirements of § 93.105(c)(1)(i) and the methodology requirements of § 93.123.

§ 93.117 Criteria and procedures: Compliance with PM_{10} control measures.

The FHWA/FTA project must comply with PM_{10} control measures in the applicable implementation plan. This criterion is satisfied if the project-level conformity determination contains a written commitment from the project sponsor to include in the final plans, specifications, and estimates for the project those control measures (for the purpose of limiting PM_{10} emissions from the construction activities and/or normal use and operation associated with the project) that are contained in the applicable implementation plan.

§ 93.118 Criteria and procedures: Motor vehicle emissions budget.

(a) The transportation plan, TIP, and project not from a conforming transportation plan and TIP must be consistent with the motor vehicle emissions budget(s) in the applicable implementation plan (or implementation plan submission). This criterion applies as described in § 93.109 (c)–(g). This criterion is satisfied if it is demonstrated that emissions of the pollutants or pollutant precursors described in paragraph (c) of this section are less than or equal to the motor vehicle emissions budget(s) established in the applicable implementation plan or implementation plan submission.

(b) Consistency with the motor vehicle emissions budget(s) must be demonstrated for each year for which the applicable (and/or submitted) implementation plan specifically establishes motor vehicle emissions budget(s), for the last year of the transportation plan's forecast period, and for any intermediate years as necessary so that the years for which consistency is demonstrated are no more than ten years apart, as follows:

(1) Until a maintenance plan is submitted:

(i) Emissions in each year (such as milestone years and the attainment year) for which the control strategy implementation plan revision establishes motor vehicle emissions budget(s) must be less than or equal to that year's motor vehicle emissions budget(s); and

(ii) Emissions in years for which no motor vehicle emissions budget(s) are specifically established must be less than or equal to the motor vehicle emissions budget(s) established for the most recent prior year. For example, emissions in years after the attainment year for which the SIP does not establish a budget must be less than or equal to the motor vehicle emissions budget(s) for the attainment year.

(2) When a maintenance plan has been submitted:

(i) Emissions must be less than or equal to the motor vehicle emissions budget(s) established for the last year of the maintenance plan, and for any other years for which the maintenance plan establishes motor vehicle emissions budgets. If the maintenance plan does not establish motor vehicle emissions budgets for any years other than the last year of the maintenance plan, the demonstration of consistency with the motor vehicle emissions budget(s) must be accompanied by a qualitative finding that there are no factors which would cause or contribute to a new violation or exacerbate an existing violation in the years before the last year of the maintenance plan. The interagency consultation process required by § 93.105 shall determine what must be considered in order to make such a finding;

(ii) For years after the last year of the maintenance plan, emissions must be less than or equal to the maintenance plan's motor vehicle emissions budget(s) for the last year of the maintenance plan; and

(iii) If an approved control strategy implementation plan has established motor vehicle emissions budgets for years in the timeframe of the transportation plan, emissions in these years must be less than or equal to the control strategy implementation plan's motor vehicle emissions budget(s) for these years.

(c) Consistency with the motor vehicle emissions budget(s) must be demonstrated for each pollutant or pollutant precursor in § 93.102(b)(3) for which the area is in nonattainment or maintenance and for which the applicable implementation plan (or implementation plan submission) establishes a motor vehicle emissions budget.

(d) Consistency with the motor vehicle emissions budget(s) must be demonstrated by including emissions from the entire transportation system, including all regionally significant projects contained in the transportation plan and all other regionally significant highway and transit projects expected in the nonattainment or maintenance area in the timeframe of the transportation plan.

(1) Consistency with the motor vehicle emissions budget(s) must be demonstrated with a regional emissions analysis that meets the requirements of §§ 93.122 and 93.105(c)(1)(i).

(2) The regional emissions analysis may be performed for any years in the timeframe of the transportation plan provided they are not more than ten years apart and provided the analysis is performed for the attainment year (if it is in the timeframe of the transportation plan) and the last year of the plan's forecast period. Emissions in years for which consistency with motor vehicle emissions budgets must be demonstrated, as required in paragraph (b) of this section, may be determined by interpolating between the years for which the regional emissions analysis is performed.

(e) Motor vehicle emissions budgets in submitted control strategy implementation plan revisions and submitted maintenance plans.

(1) Consistency with the motor vehicle emissions budgets in submitted control strategy implementation plan revisions or maintenance plans must be demonstrated if EPA has declared the motor vehicle emissions budget(s) adequate for transportation conformity purposes, or beginning 45 days after the control strategy implementation plan revision or maintenance plan has been submitted (unless EPA has declared the motor vehicle emissions budget(s) inadequate for transportation conformity purposes). However, submitted implementation plans do not supersede the motor vehicle emissions budgets in approved implementation plans for the years addressed by the approved implementation plan.

(2) If EPA has declared an implementation plan submission's motor vehicle emissions budget(s) inadequate for transportation conformity purposes, the inadequate budget(s) shall not be used to satisfy the requirements of this section. Consistency with the previously established motor vehicle emissions budget(s) must be demonstrated. If there are no previous approved implementation plans or implementation plan submissions with motor vehicle emissions budgets, the emission reduction tests required by § 93.119 must be satisfied.

(3) If EPA declares an implementation plan submission's motor vehicle emissions budget(s) inadequate for transportation conformity purposes more than 45 days after its submission to EPA, and conformity of a transportation plan or TIP has already

been determined by DOT using the budget(s), the conformity determination will remain valid. Projects included in that transportation plan or TIP could still satisfy §§ 93.114 and 93.115, which require a currently conforming transportation plan and TIP to be in place at the time of a project's conformity determination and that projects come from a conforming transportation plan and TIP.

(4) When the motor vehicle emissions budget(s) used to satisfy the requirements of this section are established by an implementation plan submittal that has not yet been approved or disapproved by EPA, the MPO and DOT's conformity determination will be deemed to be a statement that the MPO and DOT are not aware of any information that would indicate that emissions consistent with the motor vehicle emissions budget will cause or contribute to any new violation of any standard; increase the frequency or severity of any existing violation of any standard; or delay timely attainment of any standard or any required interim emission reductions or other milestones.

§ 93.119 Criteria and procedures: Emission reductions in areas without motor vehicle emissions budgets.

(a) The transportation plan, TIP, and project not from a conforming transportation plan and TIP must contribute to emissions reductions. This criterion applies as described in § 93.109 (c)–(g). It applies to the net effect of the action (transportation plan, TIP, or project not from a conforming transportation plan and TIP) on motor vehicle emissions from the entire transportation system.

(b) This criterion may be met in moderate and above ozone nonattainment areas that are subject to the reasonable further progress requirements of Clean Air Act section 182(b)(1) and in moderate with design value greater than 12.7 ppm and serious CO nonattainment areas if a regional emissions analysis that satisfies the requirements of § 93.12 2 and paragraphs (e) through (h) of this section demonstrates that for each analysis year and for each of the pollutants described in paragraph (d) of this section:

(1) The emissions predicted in the ''Action'' scenario are less than the emissions predicted in the ''Baseline'' scenario, and this can be reasonably expected to be true in the periods between the analysis years; and

(2) The emissions predicted in the ''Action'' scenario are lower than 1990 emissions by any nonzero amount.

(c) This criterion may be met in PM_{10} and NO_2 nonattainment areas; marginal and below ozone nonattainment areas and other ozone nonattainment areas that are not subject to the reasonable further progress requirements of Clean Air Act section 182(b)(1), and moderate with design value less than 12.7 ppm and below CO nonattainment areas if a regional emissions analysis that satisfies the requirements of § 93.122 and paragraphs (e) through (h) of this section demonstrates that for each analysis year and for each of the pollutants described in paragraph (d) of this section, one of the following requirements is met:

(1) The emissions predicted in the ''Action'' scenario are less than the emissions predicted in the ''Baseline'' scenario, and this can be reasonably expected to be true in the periods between the analysis years; or

(2) The emissions predicted in the ''Action'' scenario are not greater than baseline emissions. Baseline emissions are those estimated to have occurred during calendar year 1990, unless the conformity implementation plan revision required by § 51.390 of this chapter defines the baseline emissions for a PM_{10} area to be those occurring in a different calendar year for which a baseline emissions inventory was developed for the purpose of developing a control strategy implementation plan.

(d) Pollutants. The regional emissions analysis must be performed for the following pollutants:

(1) VOC in ozone nonattainment areas;

(2) NO_X in ozone nonattainment areas, unless the EPA Administrator determines that additional reductions of NO_X would not contribute to attainment;

(3) CO in CO nonattainment areas;

(4) PM_{10} in PM_{10} areas;

(5) Transportation-related precursors of PM_{10} in PM_{10} nonattainment areas if the EPA Regional Administrator or the director of the State air agency has made a finding that such precursor emissions from within the nonattainment area are a significant contributor to the PM_{10} nonattainment problem and has so notified the MPO and DOT; and

(6) NO_X in NO_2 nonattainment areas.

(e) Analysis years. The regional emissions analysis must be performed for analysis years that are no more than ten years apart. The first analysis year must be no more than five years beyond the year in which the conformity determination is being made. The last year of transportation plan's forecast period must also be an analysis year.

(f) ''Baseline'' scenario. The regional emissions analysis required by paragraphs (b) and (c)(1) of this section must estimate the emissions that would result from the ''Baseline'' scenario in each analysis year. The ''Baseline'' scenario must be defined for each of the analysis years. The ''Baseline'' scenario is the future transportation system that will result from current programs, including the following (except that exempt projects listed in § 93.126 and projects exempt from regional emissions analysis as listed in § 93.127 need not be explicitly considered):

(1) All in-place regionally significant highway and transit facilities, services and activities;

(2) All ongoing travel demand management or transportation system management activities; and

(3) Completion of all regionally significant projects, regardless of funding source, which are currently under construction or are undergoing right-of-way acquisition (except for hardship acquisition and protective buying); come from the first year of the previously conforming transportation plan and/or TIP; or have completed the NEPA process.

(g) ''Action'' scenario. The regional emissions analysis must estimate the emissions that would result from the ''Action'' scenario in each analysis year. The ''Action'' scenario must be defined for each of the analysis years. The ''Action'' scenario is the transportation system that would result from the implementation of the proposed action (transportation plan, TIP, or project not from a conforming transportation plan and TIP) and all other expected regionally significant projects in the nonattainment area. The ''Action'' scenario must include the following (except that exempt projects listed in § 93.126 and projects exempt from regional emissions analysis as listed in § 93.127 need not be explicitly considered):

(1) All facilities, services, and activities in the ''Baseline'' scenario;

(2) Completion of all TCMs and regionally significant projects (including facilities, services, and activities) specifically identified in the proposed transportation plan which will be operational or in effect in the analysis year, except that regulatory TCMs may not be assumed to begin at a future time unless the regulation is already adopted by the enforcing jurisdiction or the TCM is identified in the applicable implementation plan;

(3) All travel demand management programs and transportation system management activities known to the MPO, but not included in the applicable implementation plan or utilizing any Federal funding or approval, which have been fully adopted and/or funded by the enforcing jurisdiction or

sponsoring agency since the last conformity determination;

(4) The incremental effects of any travel demand management programs and transportation system management activities known to the MPO, but not included in the applicable implementation plan or utilizing any Federal funding or approval, which were adopted and/or funded prior to the date of the last conformity determination, but which have been modified since then to be more stringent or effective;

(5) Completion of all expected regionally significant highway and transit projects which are not from a conforming transportation plan and TIP; and

(6) Completion of all expected regionally significant non-FHWA/FTA highway and transit projects that have clear funding sources and commitments leading toward their implementation and completion by the analysis year.

(h) Projects not from a conforming transportation plan and TIP. For the regional emissions analysis required by paragraphs (b) and (c)(1) of this section, if the project which is not from a conforming transportation plan and TIP is a modification of a project currently in the plan or TIP, the ''Baseline'' scenario must include the project with its original design concept and scope, and the ''Action'' scenario must include the project with its new design concept and scope.

§ 93.120 Consequences of control strategy implementation plan failures.

(a) *Disapprovals.* (1) If EPA disapproves any submitted control strategy implementation plan revision (with or without a protective finding), the conformity status of the transportation plan and TIP shall lapse on the date that highway sanctions as a result of the disapproval are imposed on the nonattainment area under section 179(b)(1) of the Clean Air Act. No new transportation plan, TIP, or project may be found to conform until another control strategy implementation plan revision fulfilling the same Clean Air Act requirements is submitted and conformity to this submission is determined.

(2) If EPA disapproves a submitted control strategy implementation plan revision without making a protective finding, then beginning 120 days after such disapproval, only projects in the first three years of the currently conforming transportation plan and TIP may be found to conform. This means that beginning 120 days after disapproval without a protective finding, no transportation plan, TIP, or project not in the first three years of the currently conforming plan and TIP may be found to conform until another control strategy implementation plan revision fulfilling the same Clean Air Act requirements is submitted and conformity to this submission is determined. During the first 120 days following EPA's disapproval without a protective finding, transportation plan, TIP, and project conformity determinations shall be made using the motor vehicle emissions budget in the disapproved control strategy implementation plan, unless another control strategy implementation plan revision has been submitted and its motor vehicle emissions budget applies for transportation conformity purposes, pursuant to § 93.109.

(b) *Failure to submit and incompleteness.* In areas where EPA notifies the State, MPO, and DOT of the State's failure to submit a control strategy implementation plan or submission of an incomplete control strategy implementation plan revision (either of which initiates the sanction process under Clean Air Act sections 179 or 110(m)), the conformity status of the transportation plan and TIP shall lapse on the date that highway sanctions are imposed on the nonattainment area for such failure under section 179(b)(1) of the Clean Air Act, unless the failure has been remedied and acknowledged by a letter from the EPA Regional Administrator.

(c) *Federal implementation plans.* If EPA promulgates a Federal implementation plan that contains motor vehicle emissions budget(s) as a result of a State failure, the conformity lapse imposed by this section because of that State failure is removed.

§ 93.121 Requirements for adoption or approval of projects by other recipients of funds designated under title 23 U.S.C. or the Federal Transit Laws.

(a) Except as provided in paragraph (b) of this section, no recipient of Federal funds designated under title 23 U.S.C. or the Federal Transit Laws shall adopt or approve a regionally significant highway or transit project, regardless of funding source, unless the recipient finds that the requirements of one of the following paragraphs are met:

(1) The project was included in the regional emissions analysis supporting the most recent transportation plan and TIP conformity determination (even if conformity status is currently lapsed), and the project's design concept and scope has not changed significantly from those analyses; or

(2) There is a currently conforming transportation plan and TIP, and a new regional emissions analysis including the project and the currently conforming transportation plan and TIP demonstrates that the transportation plan and TIP would still conform if the project were implemented (consistent with the requirements of §§ 93.118 and/or 93.119 for a project not from a conforming transportation plan and TIP).

(b) In isolated rural nonattainment and maintenance areas subject to § 93.109(g), no recipient of Federal funds designated under title 23 U.S.C. or the Federal Transit Laws shall adopt or approve a regionally significant highway or transit project, regardless of funding source, unless the recipient finds that the requirements of one of the following paragraphs are met:

(1) The project was included in the regional emissions analysis supporting the most recent conformity determination for the portion of the statewide transportation plan and TIP which are in the nonattainment or maintenance area, and the project's design concept and scope has not changed significantly; or

(2) A new regional emissions analysis including the project and all other regionally significant projects expected in the nonattainment or maintenance area demonstrates that those projects in the statewide transportation plan and statewide TIP which are in the nonattainment or maintenance area would still conform if the project were implemented (consistent with the requirements of §§ 93.118 and/or 93.119 for projects not from a conforming transportation plan and TIP).

§ 93.122 Procedures for determining regional transportation-related emissions.

(a) General requirements. (1) The regional emissions analysis required by §§ 93.118 and 93.119 for the transportation plan, TIP, or project not from a conforming plan and TIP must include all regionally significant projects expected in the nonattainment or maintenance area. The analysis shall include FHWA/FTA projects proposed in the transportation plan and TIP and all other regionally significant projects which are disclosed to the MPO as required by § 93.105. Projects which are not regionally significant are not required to be explicitly modeled, but vehicles miles traveled (VMT) from such projects must be estimated in accordance with reasonable professional practice. The effects of TCMs and similar projects that are not regionally significant may also be estimated in accordance with reasonable professional practice.

(2) The emissions analysis may not include for emissions reduction credit any TCMs or other measures in the applicable implementation plan which have been delayed beyond the scheduled date(s) until such time as their implementation has been assured. If the measure has been partially implemented and it can be demonstrated that it is providing quantifiable emission reduction benefits, the emissions analysis may include that emissions reduction credit.

(3) Emissions reduction credit from projects, programs, or activities which require a regulatory action in order to be implemented may not be included in the emissions analysis unless:

(i) The regulatory action is already adopted by the enforcing jurisdiction;

(ii) The project, program, or activity is included in the applicable implementation plan;

(iii) The control strategy implementation plan submission or maintenance plan submission that establishes the motor vehicle emissions budget(s) for the purposes of § 93.118 contains a commitment to the project, program, or activity by the agency with authority to implement it; or

(iv) EPA has approved an opt-in to a Federally enforced program, EPA has promulgated the program (if the control program is a Federal responsibility, such as vehicle tailpipe standards), or the Clean Air Act requires the program without need for individual State action and without any discretionary authority for EPA to set its stringency, delay its effective date, or not implement the program.

(4) Emissions reduction credit from control measures that are not included in the transportation plan and TIP and that do not require a regulatory action in order to be implemented may not be included in the emissions analysis unless the conformity determination includes written commitments to implementation from the appropriate entities.

(i) Persons or entities voluntarily committing to control measures must comply with the obligations of such commitments.

(ii) The conformity implementation plan revision required in § 51.390 of this chapter must provide that written commitments to control measures that are not included in the transportation plan and TIP must be obtained prior to a conformity determination and that such commitments must be fulfilled.

(5) A regional emissions analysis for the purpose of satisfying the requirements of § 93.119 must make the same assumptions in both the ''Baseline'' and ''Action'' scenarios regarding control measures that are external to the transportation system itself, such as vehicle tailpipe or evaporative emission standards, limits on gasoline volatility, vehicle inspection and maintenance programs, and oxygenated or reformulated gasoline or diesel fuel.

(6) The ambient temperatures used for the regional emissions analysis shall be consistent with those used to establish the emissions budget in the applicable implementation plan. All other factors, for example the fraction of travel in a hot stabilized engine mode, must be consistent with the applicable implementation plan, unless modified after interagency consultation according to § 93.105(c)(1)(i) to incorporate additional or more geographically specific information or represent a logically estimated trend in such factors beyond the period considered in the applicable implementation plan.

(7) Reasonable methods shall be used to estimate nonattainment area vehicle miles traveled on off-network roadways within the urban transportation planning area, and on roadways outside the urban transportation planning area.

(b) Regional emissions analysis in serious, severe, and extreme ozone nonattainment areas and serious CO nonattainment areas must meet the requirements of paragraphs (b) (1) and (2) of this section if their metropolitan planning area contains an urbanized area population over 200,000.

(1) By January 1, 1997, estimates of regional transportation-related emissions used to support conformity determinations must be made at a minimum using network modeling according to procedures and methods that are available and in practice and supported by current and available documentation. These procedures, methods, and practices are available from DOT and will be updated periodically. Areas performing network modeling with some or all procedures and methods that are available and in practice elsewhere as of January 1, 1995, must continue to do so.

(2) Reasonable methods in accordance with good practice must be used to estimate traffic speeds and delays in a manner that is sensitive to the estimated volume of travel on each roadway segment represented in the network model.

(3) Highway Performance Monitoring System (HPMS) estimates of VMT shall be considered the primary measure of VMT within the portion of the nonattainment or maintenance area and for the functional classes of roadways included in HPMS, for urban areas which are sampled on a separate urban area basis. For areas with network models, a factor (or factors) may be developed to reconcile and calibrate the network-based model estimates of VMT in the base year of its validation to the HPMS estimates for the same period. These factors may then be applied to model estimates of future VMT. In this factoring process, consideration will be given to differences in the facility coverage of the HPMS and the modeled network description. Locally developed count-based programs and other departures from these procedures are permitted subject to the interagency consultation procedures of § 93.105(c)(1)(i).

(4) A transportation plan and TIP may satisfy the requirements of §§ 93.118 and 93.119 based on an alternate emissions analysis that does not use network modeling, if Federal, State, and local air and transportation agencies concur in the emissions analysis approach, and if the transportation plan and TIP in question is a revision of the previously conforming transportation plan and TIP to include a limited number of additional projects. This paragraph will not be effective until EPA and DOT review and evaluate suggested alternate methods and approaches for determining the regional emissions impact of projects and make documentation of this review and evaluation publicly available.

(5) A conformity determination based on an alternate emissions analysis as described in paragraph (b)(4) of this section would not fulfill the requirements of § 93.104(b)(3) and § 93.104(c)(3) regarding frequency of conformity determinations. Conformity must be determined according to all the otherwise applicable criteria and procedures of this subpart within three years of the last determination which did not rely on paragraph (b)(4) of this section.

(c) In all areas not otherwise subject to paragraph (b) of this section, regional emissions analyses must use those procedures described in paragraph (b) of this section if the use of those procedures has been the previous practice of the MPO. Otherwise, areas not subject to paragraph (b) of this section may estimate regional emissions using any appropriate methods that account for VMT growth by, for example, extrapolating historical VMT or projecting future VMT by considering growth in population and historical growth trends for vehicle miles traveled per person. These methods must also consider future economic activity, transit alternatives, and transportation system policies.

(d) PM_{10} from construction-related fugitive dust.

(1) For areas in which the implementation plan does not identify construction-related fugitive PM_{10} as a contributor to the nonattainment problem, the fugitive PM_{10} emissions associated with highway and transit project construction are not required to be considered in the regional emissions analysis.

(2) In PM_{10} nonattainment and maintenance areas with implementation plans which identify construction-related fugitive PM_{10} as a contributor to the nonattainment problem, the regional PM_{10} emissions analysis shall consider construction-related fugitive PM_{10} and shall account for the level of construction activity, the fugitive PM_{10} control measures in the applicable implementation plan, and the dust-producing capacity of the proposed activities.

(e) Reliance on previous regional emissions analysis. (1) The TIP may be demonstrated to satisfy the requirements of § 93.118 (''Motor vehicle emissions budget'') or § 93.119 (''Emission reductions in areas without motor vehicle emissions budgets'') without new regional emissions analysis if the regional emissions analysis already performed for the plan also applies to the TIP. This requires a demonstration that:

(i) The TIP contains all projects which must be started in the TIP's timeframe in order to achieve the highway and transit system envisioned by the transportation plan;

(ii) All TIP projects which are regionally significant are included in the transportation plan with design concept and scope adequate to determine their contribution to the transportation plan's regional emissions at the time of the transportation plan's conformity determination; and

(iii) The design concept and scope of each regionally significant project in the TIP is not significantly different from that described in the transportation plan.

(2) A project which is not from a conforming transportation plan and a conforming TIP may be demonstrated to satisfy the requirements of § 93.118 or § 93.119 without additional regional emissions analysis if allocating funds to the project will not delay the implementation of projects in the transportation plan or TIP which are necessary to achieve the highway and transit system envisioned by the transportation plan, and if the project is either:

(i) Not regionally significant; or

(ii) Included in the conforming transportation plan (even if it is not specifically included in the latest conforming TIP) with design concept and scope adequate to determine its contribution to the transportation plan's regional emissions at the time of the transportation plan's conformity determination, and the design concept and scope of the project is not significantly different from that described in the transportation plan.

§ 93.123 Procedures for determining localized CO and PM_{10} concentrations (hot-spot analysis).

(a) *CO hot-spot analysis.* (1) The demonstrations required by § 93.116 (''Localized CO and PM_{10} violations'') must be based on quantitative analysis using the applicable air quality models, data bases, and other requirements specified in 40 CFR part 51 Appendix W (''Guideline on Air Quality Models (Revised)'' (1988), supplement A (1987) and supplement B (1993), EPA publication no. 450/2–78–027R). These procedures shall be used in the following cases, unless different procedures are developed through the interagency consultation process required in § 93.105 and approved by the EPA Regional Administrator:

(i) For projects in or affecting locations, areas, or categories of sites which are identified in the applicable implementation plan as sites of violation or possible violation;

(ii) For projects affecting intersections that are at Level-of-Service D, E, or F, or those that will change to Level-of-Service D, E, or F because of increased traffic volumes related to the project;

(iii) For any project affecting one or more of the top three intersections in the nonattainment or maintenance area with highest traffic volumes, as identified in the applicable implementation plan; and

(iv) For any project affecting one or more of the top three intersections in the nonattainment or maintenance area with the worst level of service, as identified in the applicable implementation plan.

(2) In cases other than those described in paragraph (a)(1) of this section, the demonstrations required by § 93.116 may be based on either:

(i) Quantitative methods that represent reasonable and common professional practice; or

(ii) A qualitative consideration of local factors, if this can provide a clear demonstration that the requirements of § 93.116 are met.

(b) *PM_{10} hot-spot analysis:* (1) The hot-spot demonstration required by § 93.116 must be based on quantitative analysis methods for the following types of projects:

(i) Projects which are located at sites at which violations have been verified by monitoring;

(ii) Projects which are located at sites which have vehicle and roadway emission and dispersion characteristics that are essentially identical to those of sites with verified violations (including sites near one at which a violation has been monitored); and

(iii) New or expanded bus and rail terminals and transfer points which increase the number of diesel vehicles congregating at a single location require hot-spot analysis.

(2) Where quantitative analysis methods are not required, the demonstration required by § 93.116 may be based on a qualitative consideration of local factors.

(3) The identification of the sites described in paragraph (b)(1) (i) and (ii) of this section, and other cases where quantitative methods are appropriate, shall be determined through the interagency consultation process required in § 93.105. DOT may choose to make a categorical conformity determination on bus and rail terminals or transfer points based on appropriate modeling of various terminal sizes, configurations, and activity levels.

(4) The requirements for quantitative analysis contained in paragraph (b) of this section will not take effect until EPA releases modeling guidance on this subject and announces in the Federal Register that these requirements are in effect.

(c) *General requirements.* (1) Estimated pollutant concentrations must be based on the total emissions burden which may result from the implementation of the project, summed together with future background concentrations. The total concentration must be estimated and analyzed at appropriate receptor locations in the area substantially affected by the project.

(2) Hot-spot analyses must include the entire project, and may be performed only after the major design features which will significantly impact concentrations have been identified. The future background concentration should be estimated by multiplying current background by the ratio of future to current traffic and the ratio of future to current emission factors.

(3) Hot-spot analysis assumptions must be consistent with those in the regional emissions analysis for those inputs which are required for both analyses.

(4) PM_{10} or CO mitigation or control measures shall be assumed in the hot-

spot analysis only where there are written commitments from the project sponsor and/or operator to implement such measures, as required by § 93.125(a).

(5) CO and PM_{10} hot-spot analyses are not required to consider construction-related activities which cause temporary increases in emissions. Each site which is affected by construction-related activities shall be considered separately, using established ''Guideline'' methods. Temporary increases are defined as those which occur only during the construction phase and last five years or less at any individual site.

§ 93.124 Using the motor vehicle emissions budget in the applicable implementation plan (or implementation plan submission).

(a) In interpreting an applicable implementation plan (or implementation plan submission) with respect to its motor vehicle emissions budget(s), the MPO and DOT may not infer additions to the budget(s) that are not explicitly intended by the implementation plan (or submission). Unless the implementation plan explicitly quantifies the amount by which motor vehicle emissions could be higher while still allowing a demonstration of compliance with the milestone, attainment, or maintenance requirement and explicitly states an intent that some or all of this additional amount should be available to the MPO and DOT in the emissions budget for conformity purposes, the MPO may not interpret the budget to be higher than the implementation plan's estimate of future emissions. This applies in particular to applicable implementation plans (or submissions) which demonstrate that after implementation of control measures in the implementation plan:

(1) Emissions from all sources will be less than the total emissions that would be consistent with a required demonstration of an emissions reduction milestone;

(2) Emissions from all sources will result in achieving attainment prior to the attainment deadline and/or ambient concentrations in the attainment deadline year will be lower than needed to demonstrate attainment; or

(3) Emissions will be lower than needed to provide for continued maintenance.

(b) If an applicable implementation plan submitted before November 24, 1993, demonstrates that emissions from all sources will be less than the total emissions that would be consistent with attainment and quantifies that ''safety margin,'' the State may submit a SIP revision which assigns some or all of this safety margin to highway and transit mobile sources for the purposes of conformity. Such a SIP revision, once it is endorsed by the Governor and has been subject to a public hearing, may be used for the purposes of transportation conformity before it is approved by EPA.

(c) A conformity demonstration shall not trade emissions among budgets which the applicable implementation plan (or implementation plan submission) allocates for different pollutants or precursors, or among budgets allocated to motor vehicles and other sources, without a SIP revision or a SIP which establishes mechanisms for such trades.

(d) If the applicable implementation plan (or implementation plan submission) estimates future emissions by geographic subarea of the nonattainment area, the MPO and DOT are not required to consider this to establish subarea budgets, unless the applicable implementation plan (or implementation plan submission) explicitly indicates an intent to create such subarea budgets for the purposes of conformity.

(e) If a nonattainment area includes more than one MPO, the SIP may establish motor vehicle emissions budgets for each MPO, or else the MPOs must collectively make a conformity determination for the entire nonattainment area.

§ 93.125 Enforceability of design concept and scope and project-level mitigation and control measures.

(a) Prior to determining that a transportation project is in conformity, the MPO, other recipient of funds designated under title 23 U.S.C. or the Federal Transit Laws, FHWA, or FTA must obtain from the project sponsor and/or operator written commitments to implement in the construction of the project and operation of the resulting facility or service any project-level mitigation or control measures which are identified as conditions for NEPA process completion with respect to local PM_{10} or CO impacts. Before a conformity determination is made, written commitments must also be obtained for project-level mitigation or control measures which are conditions for making conformity determinations for a transportation plan or TIP and are included in the project design concept and scope which is used in the regional emissions analysis required by §§ 93.118 (''Motor vehicle emissions budget'') and 93.119 (''Emission reductions in areas without motor vehicle emissions budgets'') or used in the project-level hot-spot analysis required by § 93.116.

(b) Project sponsors voluntarily committing to mitigation measures to facilitate positive conformity determinations must comply with the obligations of such commitments.

(c) The implementation plan revision required in § 51.390 of this chapter shall provide that written commitments to mitigation measures must be obtained prior to a positive conformity determination, and that project sponsors must comply with such commitments.

(d) If the MPO or project sponsor believes the mitigation or control measure is no longer necessary for conformity, the project sponsor or operator may be relieved of its obligation to implement the mitigation or control measure if it can demonstrate that the applicable hot-spot requirements of § 93.116, emission budget requirements of § 93.118, and emission reduction requirements of § 93.119 are satisfied without the mitigation or control measure, and so notifies the agencies involved in the interagency consultation process required under § 93.105. The MPO and DOT must find that the transportation plan and TIP still satisfy the applicable requirements of §§ 93.118 and/or 93.119 and that the project still satisfies the requirements of § 93.116, and therefore that the conformity determinations for the transportation plan, TIP, and project are still valid. This finding is subject to the applicable public consultation requirements in § 93.105(e) for conformity determinations for projects.

§ 93.126 Exempt projects.

Notwithstanding the other requirements of this subpart, highway and transit projects of the types listed in Table 2 are exempt from the requirement to determine conformity. Such projects may proceed toward implementation even in the absence of a conforming transportation plan and TIP. A particular action of the type listed in Table 2 is not exempt if the MPO in consultation with other agencies (see § 93.105(c)(1)(iii)), the EPA, and the FHWA (in the case of a highway project) or the FTA (in the case of a transit project) concur that it has potentially adverse emissions impacts for any reason. States and MPOs must ensure that exempt projects do not interfere with TCM implementation.

TABLE 2.—EXEMPT PROJECTS

Safety
Railroad/highway crossing.
Hazard elimination program.
Safer non-Federal-aid system roads.
Shoulder improvements.
Increasing sight distance.
Safety improvement program.
Traffic control devices and operating assistance other than signalization projects.
Railroad/highway crossing warning devices.
Guardrails, median barriers, crash cushions.
Pavement resurfacing and/or rehabilitation.
Pavement marking demonstration.
Emergency relief (23 U.S.C. 125).
Fencing.
Skid treatments.
Safety roadside rest areas.
Adding medians.
Truck climbing lanes outside the urbanized area.
Lighting improvements.
Widening narrow pavements or reconstructing bridges (no additional travel lanes).
Emergency truck pullovers.
Mass Transit
Operating assistance to transit agencies.
Purchase of support vehicles.
Rehabilitation of transit vehicles.[1]
Purchase of office, shop, and operating equipment for existing facilities.
Purchase of operating equipment for vehicles (e.g., radios, fareboxes, lifts, etc.).
Construction or renovation of power, signal, and communications systems.
Construction of small passenger shelters and information kiosks.
Reconstruction or renovation of transit buildings and structures (e.g., rail or bus buildings, storage and maintenance facilities, stations, terminals, and ancillary structures).
Rehabilitation or reconstruction of track structures, track, and trackbed in existing rights-of-way.
Purchase of new buses and rail cars to replace existing vehicles or for minor expansions of the fleet.[1]
Construction of new bus or rail storage/maintenance facilities categorically excluded in 23 CFR part 771.
Air Quality
Continuation of ride-sharing and van-pooling promotion activities at current levels.
Bicycle and pedestrian facilities.
Other
Specific activities which do not involve or lead directly to construction, such as:
Planning and technical studies.
Grants for training and research programs.
Planning activities conducted pursuant to titles 23 and 49 U.S.C.
Federal-aid systems revisions.
Engineering to assess social, economic, and environmental effects of the proposed action or alternatives to that action.
Noise attenuation.
Emergency or hardship advance land acquisitions (23 CFR 712.204(d)).
Acquisition of scenic easements.
Plantings, landscaping, etc.
Sign removal.
Directional and informational signs.
Transportation enhancement activities (except rehabilitation and operation of historic transportation buildings, structures, or facilities).
Repair of damage caused by natural disasters, civil unrest, or terrorist acts, except projects involving substantial functional, locational or capacity changes.

[1] In PM_{10} nonattainment or maintenance areas, such projects are exempt only if they are in compliance with control measures in the applicable implementation plan.

§ 93.127 Projects exempt from regional emissions analyses.

Notwithstanding the other requirements of this subpart, highway and transit projects of the types listed in Table 3 are exempt from regional emissions analysis requirements. The local effects of these projects with respect to CO or PM_{10} concentrations must be considered to determine if a hot-spot analysis is required prior to making a project-level conformity determination. These projects may then proceed to the project development process even in the absence of a conforming transportation plan and TIP. A particular action of the type listed in Table 3 is not exempt from regional

emissions analysis if the MPO in consultation with other agencies (see § 93.105(c)(1)(iii)), the EPA, and the FHWA (in the case of a highway project) or the FTA (in the case of a transit project) concur that it has potential regional impacts for any reason.

TABLE 3.—PROJECTS EXEMPT FROM REGIONAL EMISSIONS ANALYSES

Intersection channelization projects.
Intersection signalization projects at individual intersections.
Interchange reconfiguration projects.
Changes in vertical and horizontal alignment.
Truck size and weight inspection stations.
Bus terminals and transfer points.

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Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 106 and 107

Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for the Production of Infant Formula; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 106 and 107

[Docket No. 95N–0309]

RIN 0910–AA04

Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for the Production of Infant Formula

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revise its infant formula regulations to establish requirements for quality factors and current good manufacturing practice (CGMP); to amend its quality control procedure, notification, and records and report requirements for infant formulas; to require that infant formulas contain, and be tested for, required nutrients and for any nutrient added by the manufacturer throughout their shelf life, and that they be produced under strict microbiological controls; and to require that manufacturers implement the CGMP and quality control procedure requirements by establishing a production and in-process control system of their own design. This action is being taken to improve the protection of infants that use infant formula products.

DATES: Comments by October 7, 1996, except that comments regarding information collection should be submitted by August 8, 1996. The agency proposes that any final rule that may issue based on this proposal become effective 120 days after its date of publication.

ADDRESSES: Submit written comments, data, or information to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Comments regarding information collection to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, ATTN: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Carolyn W. Miles, Center for Food Safety and Applied Nutrition (HFS–456), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–401–9858.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Infant Formula Act of 1980

In 1978, a major manufacturer of infant formula reformulated two of its soy products by discontinuing the addition of salt. This reformulation resulted in infant formula products that contained an inadequate amount of chloride, an essential nutrient for growth and development in infants. By mid-1979, a substantial number of infants had been diagnosed with hypochloremic metabolic alkalosis, a syndrome associated with chloride deficiency. Development of this syndrome in these infants was found to be associated with prolonged exclusive use of chloride-deficient soy formulas.

After reviewing the matter, Congress determined that, to improve protection of infants using infant formula products, greater regulatory control over the formulation and production of infant formula was needed, including modifications of industry's and FDA's recall procedures. Accordingly, Congress passed, and the President signed into law on September 26, 1980, the Infant Formula Act of 1980 (the 1980 act) (Pub. L. 96–359). This law amended the act to include section 412 (21 U.S.C. 350a).

In 1982, FDA adopted infant formula recall procedures, establishing subpart D of part 107 of its regulations (21 CFR part 107) (47 FR 18832, April 30, 1982), and infant formula quality control procedures (21 CFR part 106 (47 FR 17016, April 20, 1982)). In 1985, FDA further implemented the 1980 act by establishing subparts B, C, and D in 21 CFR part 107 regarding the labeling of infant formula, exempt infant formulas, and nutrient requirements for infant formula, respectively (50 FR 1833, January 14, 1985; 50 FR 48183, November 22, 1985; and 50 FR 45106, October 30, 1985).

B. The 1986 Amendments to the Infant Formula Act

In 1986, Congress, as part of the Drug Enforcement, Education, and Control Act of 1986 (the 1986 amendments) (Pub. L. 99–570) completely revamped section 412 of the act to address concerns that had been expressed by Congress and consumers about the 1980 act and FDA's implementation of that statute. These concerns included whether the quality control testing, CGMP, recordkeeping, and recall requirements that FDA had adopted would prevent children ''from ever again being threatened by defective baby formula'' (Ref. 1). The 1986 amendments: (1) State that an infant formula is deemed to be adulterated unless it provides certain required nutrients, meets the quality factor requirements established by the Secretary of Health and Human Services (the Secretary) (and, by delegation, FDA), and is manufactured in accordance with CGMP and quality control procedures established by the Secretary; (2) require that the Secretary issue regulations establishing requirements for quality factors and CGMP, including quality control procedures; (3) require that infant formula manufacturers regularly audit their operations to ensure that those operations comply with CGMP and quality control procedure regulations; (4) expand the circumstances in which manufacturers must make a submission to the agency to include when a manufacturer makes major changes in an infant formula, and when a manufacturer makes changes that may affect whether the formula is adulterated; (5) specify the nutrient quality control testing that must be done on each batch of infant formula; (6) modify the infant formula recall requirements; and (7) give the Secretary authority to establish requirements for retention of records, including records necessary to demonstrate compliance with CGMP and quality control procedures.

In 1989, the agency responded to the provisions of the 1986 amendments on recalls (sections 412(f) and (g) of the act) by establishing subpart E in part 107 (54 FR 4006, January 27, 1989). In 1991, the agency adopted infant formula record and record retention requirements that implemented the 1986 amendments by revising § 106.100 (56 FR 66566, December 24, 1991).

Although the agency has adopted regulations that respond to a number of the provisions of the 1986 amendments, it has not issued regulations on infant formula CGMP and quality factors or revised the notification procedures and quality control procedures to reflect the 1986 amendments. Since the passage of the 1986 amendments, agency representatives have visited infant formula plants to observe the manufacturing practice and quality control procedures that they employ, and the agency has solicited and received recommendations on CGMP from the Infant Formula Council. In addition, FDA has contracted with the Committee on Nutrition of the American Academy of Pediatrics (CON/AAP) to obtain expert advice on clinical testing of infant formulas with respect to the quality factor requirements. Moreover, both industry and the agency have

increased experience with the quantity and quality of information that should be submitted to meet the notification requirements of section 412(c) and (d) of the act.

This proposal addresses CGMP, quality control procedures, quality factors, and notification procedures and incorporates information resulting from the interactions between FDA and industry and between FDA and AAP. This proposal updates the language in part 107 to reflect the 1986 amendments and the November 1992 reorganization of the Center for Food Safety and Applied Nutrition (CFSAN).

C. FDA's Regulations on Nutrient Requirements

Section 412(i) of the act includes a table that lists nutrients that every infant formula must contain. This section also establishes a minimum level for each of the listed nutrients and a maximum level for eight of the listed nutrients. In addition, section 412(i)(2) of the act grants the Secretary (and by delegation FDA) the authority to revise the list of nutrients in section 412(i), and the minimum and maximum levels of those nutrients, by regulation. In the Federal Register of October 30, 1995, FDA established the nutrient requirements for infant formulas in § 107.100 (50 FR 45106). For the purpose of this document, the nutrients that are required to be in infant formula under § 107.100 will be referred to as ''required nutrients,'' and the levels of these required nutrients established in § 107.100 will be referred to as ''required levels.''

II. The Need for Regulation

Relative to per unit of body weight, nutrient requirements are generally greater in infancy than at any other time during life. During the first year, the rate of growth is at its maximum, with birth weight typically doubling by 4 months of age and tripling by 1 year (Refs. 2 and 3). Moreover, the metabolic rate in infants is greater, and the turnover of nutrients is more rapid, than in adults (Ref. 4). Thus, infants must ingest adequate nutrients to support a rapid rate of growth and of developmental changes and to supply maintenance needs. Without adequate nutrition, infants would be unable to achieve their genetic potential for growth and development.

These nutritional needs must be met in early infancy by food in liquid form. Sucking and involuntary swallow reflexes are the mechanisms by which very young infants ingest food until teeth and motor coordination develop. Consequently, for infants who are not fed breast milk, infant formula often serves as the sole source, or the major source, of nutrition during this time of rapid growth and development.

Therefore, the importance of proper infant formula manufacture, composition, and nutrient levels cannot be overstated. Senator Metzenbaum explained why infant formula needs more regulation than other foods when he stated ''there is simply no margin for error in the production of baby formula. An infant relies on the formula to sustain life and provide the proper nourishment at a time of rapid physical and mental development'' (Ref. 1). The requirements contained in this proposal are designed to ensure that the formula fed to American infants fulfills its important function.

The CGMP and quality control procedures that FDA is proposing are designed to prevent the production of an adulterated infant formula. Defining CGMP will help to ensure that all of the required nutrients are included at appropriate levels in the formula, and that the formula is not contaminated with microorganisms or other materials that may be harmful to the infant.

Quality control procedures are designed to ensure that an infant formula contains the nutrients that are necessary to support growth and development, at the appropriate levels, not only when it enters into commerce but throughout its shelf life. FDA is proposing that each batch of infant formula be tested for all required nutrients and any nutrient added by the manufacturer, and that finished batches be periodically sampled and tested for nutrients throughout the shelf life of the product.

Quality factors are designed to ensure that the required nutrients and any nutrient added by the manufacturer actually reach the infant in a useable form. Quality factors ''pertain to the bioavailability of a nutrient and the maintenance of level or potency of nutrients during the expected shelf life of the product'' (Ref. 5). The 1986 amendments directed that the Secretary, by regulation, ''establish requirements for quality factors for infant formulas to the extent possible consistent with current scientific knowledge, including quality factor requirements for the nutrients required by (section 412(i) of the act).''

In 1986, FDA advised Congress that the technology and science with respect to quality factors was still evolving, and that it was only possible to establish a quality factor for one nutrient. The agency said that it had already done so. However, in the 1986 Congressional Record (Ref. 1), Senator Metzenbaum stated that ''the legislation contemplates that the Secretary will move to promptly develop and issue appropriate quality factor standards for different nutrients as the state of the science progresses.'' Since that time, as stated above, FDA has contracted with CON/AAP to obtain expert advice on quality factors; i.e., on the clinical testing of infant formula with respect to its nutritional safety and suitability for term infants.

In 1988, CON/AAP submitted a report (Ref. 6) under the contract that identified and discussed the types of clinical studies that might be considered for evaluation of the nutritional suitability of a formula for normal term infants. FDA has reviewed this report and the available scientific literature and has identified quality factors for protein and for complete infant formulas. The agency is proposing to adopt these quality factors as part of these regulations.

FDA has received numerous inquiries from industry for specific guidance on what information must be submitted to meet the requirements of sections 412(c) and (d) of the act, which state when a manufacturer must register with, submit to, or notify the agency about a new or changed infant formula, and what must be in the registration, submission, or notification. The agency is responding to these requests in this proposal. The agency is providing this information not only in response to these inquiries but also to facilitate more consistent registrations, submissions, and notifications. The lack of consistency in the format and content of registrations, submissions, and notifications has caused inefficiencies and delays in the agency's review. Accordingly, the agency is proposing to establish a consistent format and content for infant formula registrations, submissions, and notifications.

Within the past year, FDA has investigated a number of instances in which infant formula manufactured in the United States has been diverted from normal distribution channels and relabeled, sometimes with counterfeit labels for the same brand of infant formula but in other instances with counterfeit labels for different formulations. Infant formula bearing counterfeit labels is a potentially serious public health problem. It could cause infant formula that is past the use by date to enter the marketplace if the counterfeit label bears an incorrect use by date. The more serious consequence of this practice, however, is that it could cause infants that are intolerant to certain infant formula ingredients to be fed an incorrect formula, with serious consequences to the health of the infant,

if an infant formula has been relabeled with an incorrect label (e.g., a milk-based infant formula relabeled to indicate that it is a soy-based infant formula). Therefore, as part of this proposed regulation, the agency is requesting comments on new or modified procedures or controls that could be instituted during the labeling, packaging, or distribution of infant formula and that would be effective in preventing or reducing the potential for the diversion of infant formula from normal distribution channels and its relabeling with counterfeit labels.

III. Scope of this Document

To implement the 1986 amendments, the agency is proposing to amend its regulations by adding new subparts B, D, and E to part 106 and by redesignating existing subparts B, C, and D as subparts C, F, and G. Table 1 sets out the current and proposed subpart designations.

TABLE 1

Subparts	Current regulation	Proposed regulation
A	General Provisions	General Provisions.
B	Quality Control Procedures for Assuring Nutrient Content of Infant Formulas.	Current Good Manufacturing Practice.
C	Records and Reports	Quality Control Procedures.
D	Notification Requirements	Conduct of Audits.
E	None	Quality Factors for Infant Formulas.
F	None	Records and Reports.
G	None	Registration, Submission, and Notification Requirements.

The proposed regulation adds a new § 107.1 and will amend § 107.10(a)(2) by requiring that ''any nutrient added by the manufacturer'' be listed on the label. The proposed regulation amends §§ 107.240 and 107.250 by changing the reference to the Division of Regulatory Guidance to the Division of Enforcement to reflect the November 1992 reorganization of CFSAN.

IV. The Proposed Regulations

A. General Provisions

To reflect the expanded scope of the proposed regulations, FDA is revising the heading of part 106 to read, ''Infant Formula-Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications.''

1. Status and Applicability of the Regulations in Part 106

Proposed § 106.1 sets out the authority for each of the proposed subparts and the consequences under the act of failure to comply with any of the regulations in the proposed subparts. FDA is including proposed § 106.1 because it is important for manufacturers to be aware of the legal consequences of failure to comply with these regulations, which are being issued to implement specific sections of the act.

2. Definitions

The agency is proposing to amend § 106.3 by adding several definitions that are needed to explain activities that specifically concern the infant formula industry. It is important whenever possible to maintain consistent terminology throughout the agency's regulations. Therefore, as described in detail below, FDA has relied, where possible, on existing definitions in 21 CFR parts 105, 110, and 210 in arriving at these proposed definitions. Other definitions were derived from specific provisions in the act.

Proposed § 106.3(a), (g), (h), and (p) incorporate into part 106 the definitions for ''batch,'' ''lot,'' ''lot number, control number, or batch number,'' and ''representative sample'' derived from 21 CFR 210.3(b)(2), (b)(10), (b)(11), and (b)(21), respectively. In addition to promoting consistency in the agency's regulations, FDA has tentatively determined that use of these definitions in part 106 is appropriate because they permit the agency to refer to the product in terms that reflect the fact that it is produced in bulk rather than on a unit-by-unit basis.

Proposed § 106.3(k), (q), and (r) incorporate into part 106 the definitions for ''microorganisms,'' ''shall,'' and ''should'' from 21 CFR 110.3(i), (p), and (q), respectively. In addition to promoting consistency, these definitions reflect the generally recognized scientific or legal meaning of these terms.

Proposed § 106.3(c), (f), (j), and (n) incorporate into part 106 the definitions for ''indicator nutrient,'' ''in-process batch,'' ''manufacturer,'' and ''nutrient premix'' from current § 106.3. The definition of ''manufacturer'' in proposed § 106.3(j) warrants particular note. In the past there has been some confusion about who is and who is not a manufacturer of infant formula. This definition makes clear that a manufacturer is not only a person who combines raw ingredients together to produce an infant formula but also is a person who reconstitutes or otherwise changes the physical or chemical characteristics of an infant formula or who packages or labels the product in a container for distribution. For example, the agency is aware of a firm that reconstitutes powdered infant formulas and puts the reconstituted formula in bottles to sell to hospitals. This definition makes clear that this firm is a ''manufacturer.''

Proposed § 106.3(d) incorporates into part 106 the definition for ''infant'' from 21 CFR 105.3(e).

In addition to the definitions derived from FDA's existing regulations, the agency is proposing to amend § 106.3 by adding definitions that are derived from the definitions provided by Congress in the act.

Proposed § 106.3(e) and (l) incorporate into part 106 the definitions for ''infant formula'' and ''new infant formula'' from sections 201(aa) (21 U.S.C. 321(aa)) and 412(c)(2), respectively.

Proposed § 106.3(e) defines ''infant formula'' as a food that purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk. The phrase ''solely as a food for infants'' is somewhat ambiguous. Where there is an ambiguity in a statutory provision, it is appropriate to look to the legislative history to determine the appropriate interpretation. In the legislative history of the Infant Formula Act, whenever the words ''sole'' or ''solely'' are used, they appear in the context of describing infant formula as the ''sole'' or primary source of nutrition for infants or babies. For example, in explaining how the

1980 act would change existing laws, then-Congressman Gore stated: ''First it would require that any infant formula marketed in the United States as the sole source of nutrition for normal babies include minimum amounts of all essential nutrients.'' (Ref. 7.) Congressman Mottl stated that the 1980 act ''is concerned with human lives at their most vulnerable stage. We are talking about food that may be the sole source of nourishment for infants.'' (Ref. 7.) This language and other similar language in the legislative history evidence that Congress intended the act to apply to any food that purports to be or that is represented as an infant formula, regardless of whether other possible uses of the product are suggested in its labeling. If the law only applied to foods that are represented only for use as infant formula, then manufacturers could easily evade the requirements of the act for infant formula by representing their products for a second purpose. Such an interpretation would be inconsistent with the remedial purposes of the infant formula provisions of the act.

Proposed § 106.3(b) incorporates into part 106 the definition for ''final-product-stage'' derived from section 412(b)(3)(E) of the act. FDA has modified the definition, however, by adding the phrase ''due to processing'' at the end of the definition to clarify that the final-product-stage is when the infant formula ''is homogeneous and is not subject to further degradation due to processing'' and to distinguish the point in time after which the formula is subject to further degradation during the shelf life of the product.

Proposed § 106.3(i) incorporates into part 106 a definition of ''major change'' that is derived from section 412(c)(2)(B) of the act, which states that ''* * * the term 'major change' has the meaning given to such term in section 106.30(c)(2) of title 21, Code of Federal Regulations (as in effect on August 1, 1986), and guidelines issued thereunder'' (Ref. 8). Proposed § 106.3(i) defines ''major change'' as it is defined in current § 106.30(c)(2). It also provides a number of examples of infant formulas deemed to differ fundamentally in processing or in composition. These examples are derived from the guidelines that were issued by the agency and were incorporated into the definition of ''major change'' in section 412(c) of the act by the 1986 amendments.

Proposed § 106.3(m) revises the definition for ''nutrient'' in current § 106.3(d) to reflect changes to the act made by the 1986 amendments. As stated above, the 1986 amendments moved the nutrient table from section 412(g) to section 412(i)(1) and moved the provision on promulgation of standards for nutrients from section 412(a)(2)(A) to section 412(i)(2). The proposed regulation references the new section numbers. Proposed § 106.3(m) also includes the statement that nutrients are substances determined to be essential by the Food and Nutrition Board of the National Research Council or by FDA. The agency is including this statement in the proposed definition to provide consistency with § 107.10(b)(5) on labeling nutrient information. This paragraph allows such information to include any vitamin or mineral in the formula, provided that the nutrient has been identified as essential by the National Academy of Sciences through its development of a recommended dietary allowance or an estimated safe and adequate daily dietary intake range, or the nutrient has been identified as essential by FDA through a Federal Register publication.

Proposed § 106.3(o) defines ''quality factors.'' The definition that FDA is proposing derives from the language of the act and its legislative history. Section 412(b)(1) of the act states that the Secretary shall ''establish requirements for quality factors for infant formulas * * *, including quality factor requirements for the nutrients required by subsection (i).'' House Report 96–936 (Ref. 5) states that quality factors ''pertain to the bioavailability of a nutrient and the maintenance of level or potency of nutrients during the expected shelf life of the product.'' The language of the act and the House report show that Congress intended that infant formulas marketed in the United States should not only be safe, and contain all of the nutrients required to support infant growth and health, but should provide those nutrients in a bioavailable form that will mean that, throughout its shelf life, the formula will support optimal infant growth and health.

Thus, quality factors encompass something different than the analyzable nutrient content of the finished infant formula. Quality factor requirements not only ensure that the nutrient potency and biological effectiveness of a formula, as formulated, are adequate to support healthy growth, but also that subsequent processing, ingredient interactions, and time do not reduce the biological effectiveness of a formula. Quality factor requirements also ensure that unsafe nutrient ''super potencies'' or by-products are not created from ingredient breakdowns or interactions caused by processing or time.

B. CGMP

1. Introduction

The agency is proposing to adopt a new subpart B to implement the CGMP requirements in section 412(b)(2) of the act. Proposed § 106.5 is introductory. It reflects FDA's tentative view that the CGMP requirements set out in subpart B are the minimum necessary to ensure that the infant formula that is produced contains all the requisite nutrients and is not otherwise adulterated.

To develop the proposed CGMP regulations, as stated above, agency representatives visited infant formula plants to observe the manufacturing practice that they employ, and the agency has solicited and received recommendations on CGMP from the infant formula industry through the Infant Formula Council (Ref. 9). The agency also is relying on its knowledge of industry manufacturing practices gained through inspections of infant formula manufacturing establishments, review of infant formula submissions received from industry since 1986, and monitoring of infant formula recalls.

The proposed CGMP regulations also are based in part on FDA's existing regulations concerning CGMP for foods (21 CFR part 110) and for drugs (21 CFR part 211). Because infant formulas are foods, they should, at a minimum, be manufactured in a manner that is consistent with CGMP for all foods under section 402(a)(4) of the act (21 U.S.C. 342(a)(4)). Moreover, infant formulas are often the sole source of nutrition for infants during a period of rapid growth and development and, hence, are used during a period of nutritional vulnerability. Thus, if the formula is to promote optimal infant health and growth, each batch of infant formula must provide the nutrients prescribed under section 412(i) of the act at the levels specified in that section, much like each batch of drugs must meet compositional requirements for active ingredients if they are to have their intended effect. Therefore, FDA has tentatively concluded that some of the manufacturing practices required of drug manufacturers are relevant to infant formula manufacturers.

2. Production and In-Process Control System

Section 412(b)(2)(B)(iii) of the act states that CGMP and quality control procedures shall include requirements for ''in-process controls including, where necessary, testing required by CGMP designed to prevent adulteration of each batch of infant formula.'' In the past, manufacturers of infant formula have referred to production and in-

process control systems intended to ensure that required nutrients are included in the formula and to prevent adulteration by such terms as ''quality control plans,'' ''standard operating procedures,'' or ''master manufacturing procedures.'' Infant formula manufacturers also have investigated adopting a system, known as the ISO.9000 series, developed by the International Organization for Standardization (ISO).

The agency is proposing to establish a framework in which decisions about the production of infant formula are left to the manufacturer but that charges the manufacturer with incorporating into its production process measures that are designed to ensure the safety and nutritional quality of the formula.

For example, proposed § 106.10(a) requires that there be sufficient personnel, qualified by training and experience, to perform all operations, including all required recordkeeping, in the manufacture, processing, packing, and holding of each infant formula and to supervise such operations to ensure that they are correctly and fully performed. This provision is a performance standard for determining how many employees are necessary, i.e., that there be enough to achieve, maintain, and document CGMP. FDA is not proposing to provide the specific number of employees required, the specific type of training that they must have, the specific task they are to perform, or the specific method by which records are to be kept.

In another example, proposed § 106.35(b)(4) requires that infant formula manufacturers ensure that automatic (mechanical or electronic) systems are validated before their first use to manufacture commercial product. However, in this provision, the agency is not stipulating any standards or specifications for the validation process because the extent of the validation that is necessary is related to the level of risk that each component of the system presents. These decisions about the validation necessary are left to the infant formula manufacturer to make.

As a third example, proposed § 106.91(b) requires that the manufacturer conduct nutrient stability testing at the beginning, midpoint, and end of the shelf life of the infant formula and with sufficient frequency to ensure that the formula complies with § 107.100 throughout its shelf life. Because manufacturers have experience with the nutrient stability of the infant formula matrices that they produce and are in a position to determine how frequently testing is necessary, the agency is proposing only to require testing ''with sufficient frequency,'' instead of specifying what frequency is required.

Proposed § 106.6(a) requires that infant formula manufacturers comply with the requirements of subpart B of part 106 by implementing a system of production and in-process controls that covers all stages of processing, from receipt and acceptance of raw materials, ingredients, and components through storage and distribution of finished product, and that is designed to ensure that all requirements of subpart B of part 106 are met.

Infant formula manufacturing requires a degree of sophistication (e.g., in research and development, production equipment and procedures, and analytical equipment and methodology) that a vast majority of companies in the food processing industry do not have. A manufacturer must maintain constant control because a seemingly innocuous change in formulation or in a preparation method, or exposure to an unanticipated environmental condition, could create a health hazard. Moreover, infant formula manufacturers must be concerned not only that something is present in the formula that may adulterate that formula, such as a contaminant or a level of a required nutrient that exceeds the maximum level allowed by § 107.100, but also that something is absent from the formula, such as the lack or unavailability of a required nutrient. For example, the lack of a nutrient or the unavailability of an added nutrient has been responsible for a number of documented problems that have occurred in infant formulas (Ref. 1). Thus, FDA has tentatively concluded that the use of a production and in-process control system covering all stages of processing is necessary to ensure that the infant formula is manufactured in a manner that will prevent adulteration of the infant formula.

Proposed § 106.6(b) requires that the production and in-process control system be set out in a written plan, or set of procedures, that is designed to ensure that the infant formula is manufactured in a manner that will prevent adulteration of the formula. FDA has tentatively concluded that requiring that the production and in-process control system be set out in a written plan or a set of procedures is necessary to provide consistency in production of different batches of infant formula and to facilitate the preparation of each batch of infant formula. Consistency is provided because the plan means that there is a single set of procedures established that are to be followed in producing the formula. The plan also facilitates preparation of the formula because, given the sophistication of the infant formula manufacturing process, a written plan to which ready and easy reference can be had is essential. The importance of a written plan is well-recognized by industry. The use of a written plan or set of procedures for production of a batch of infant formula is already a wide-spread practice.

The agency has sought to develop a basic list of items that a firm would need to consider in developing its plan or procedures, but the agency is reluctant to offer such a list at this stage of the rulemaking, before it has received comments on the proposed good manufacturing practice regulations. The agency requests comments on whether such a basic list, over and above the provisions of Subpart B itself, is possible or desirable, and if it is, what such a list should include.

The agency would conceive of such a list, at a minimum, as consisting of a number of items. It would need to direct the manufacturer to establish the safeguards that it will rely upon to protect against the foreseeable sources of adulteration in the production of infant formula. It would also need to direct the manufacturer to establish procedures for ensuring that the manufacturing process functions properly. Several of the procedures that would have to be established to do so are defined in the proposed regulations, including: (1) Procedures, in accordance with proposed § 106.35(b)(2), to calibrate, inspect, and check hardware; (2) specifications, in accordance with proposed § 106.40(d), for the acceptance or rejection of ingredients, containers, and closures used in infant formula manufacture; (3) the master manufacturing orders in accordance with proposed § 106.50(a)(1); and (4) testing procedures, under proposed § 106.55(b), to ensure that powdered infant formula complies with the microbiological quality standards. Other items that would also seem to be appropriately included on such a list would be procedures for controlling the release of product, for ensuring its traceability, and for conducting GMP audits. However, FDA requests comments on whether these items provide an adequate checklist for the development of the type of written plan that is necessary under these proposed regulations.

For now, FDA is leaving the specific content of the procedures that are in the written plan to the manufacturer's discretion. FDA requests comment on whether the agency should develop guidance on the content of any of the

procedures that are part of the written plan.

Proposed § 106.6(c) specifies requirements for a manufacturer's handling of any point, step, or stage in its production process where control of the process is necessary to prevent adulteration of the formula. These in-process control points, steps, or stages may include retorting or other heating steps, cooling steps, points where specific sanitation procedures are needed, product formulation control steps, points where cross contamination may occur, and steps where employee and environmental hygiene are necessary to prevent adulteration of the product.

Proposed § 106.6(c)(1) requires that infant formula manufacturers establish standards or specifications to be met at such points, steps, or stages. These standards or specifications establish the boundaries of safety at the point, step, or stage. Such standards or specifications may include, for example, upper and lower limits for parameters such as temperature, time, pH, visual appearance, and moisture level as well as chemical, nutrient, and microbiological specifications for raw materials. These standards or specifications can be set based on published or unpublished studies, on regulatory levels established by FDA, or on consultation with experts in infant formula production. As discussed in more detail below, FDA is proposing (see proposed § 106.100(e)(3)(i)) that manufacturers make and retain a list of the standards and specifications that they establish under proposed § 106.6(c)(1) including documentation of the scientific basis for each standard or specification. Maintaining such a list will mean that these standards and specifications are readily available for comparison to the actual values obtained in monitoring (i.e., making a planned sequence of observations or measurements) the production and in-process control system.

Proposed § 106.6(c)(2) requires that infant formula manufacturers monitor the points, steps, or stages in their production process where control is necessary to prevent adulteration of the infant formula. Regular monitoring of these points is necessary to ensure that the product meets the standards and specifications set under proposed § 106.6(c)(1) and to ensure that any trend toward loss of control is quickly identified. Quick identification will mean that adjustments can be made to prevent a deviation from occurring, or, in the event that a deviation does occur, that effective corrective actions can be taken to remove adulterated product from the system.

For many standards or specifications, continuous monitoring is possible. For example, temperature and time for a scheduled thermal process can be recorded continuously on temperature-recording charts. When it is not possible to monitor a particular point, step, or stage on a continuous basis, monitoring intervals need to be reliable enough to permit the manufacturer to determine whether the production control point is under control.

Monitoring involves not only making observations at an appropriate frequency but also ensuring that the instruments and equipment, such as thermometers, temperature-recording devices, and computer software, that the manufacturer relies on to make its observations are accurate and reliable (see proposed § 106.30(d)).

Proposed § 106.6(c)(3) requires that infant formula manufacturers establish corrective action plans for use when a standard or specification established in accordance with proposed § 106.6(c)(1) is not met. FDA has tentatively concluded that this requirement is necessary because a manufacturer will often need to take corrective action quickly, and the best way to ensure that a corrective action is appropriate is to determine the action in advance. The corrective action plans should provide, for example, for the disposition of any infant formula or of any partially manufactured infant formula that was produced when a deviation was occurring.

Proposed § 106.6(c)(4) requires that infant formula manufacturers review the results of the monitoring required under proposed § 106.6(c)(2). This review will reveal whether the monitoring is actually being done and being done correctly, and whether standards and specifications are being met.

Proposed § 106.6(c)(4) further requires that infant formula manufacturers review, and evaluate the public health significance of, any deviations from standards or specifications established in accordance with proposed § 106.6(c)(1). This proposed requirement is necessary to ensure that products that may have been affected by a deviation do not enter commerce if they are likely to be unsafe. It also will ensure that the disruption of a manufacturer's business is minimized when a deviation does occur. For example, if review of monitoring records reveals that an ingredient premix does not contain the required nutrients at the required levels, the manufacturer can take steps to dispose of the premix before it is used in the manufacture of an infant formula. If the monitoring records are not reviewed, a product made with a deficient premix may be placed on the market, and a costly and embarrassing recall may be required.

Proposed § 106.6(c)(4) also requires that this review be conducted by an individual qualified by training and experience to conduct such reviews. This proposed requirement is necessary to ensure that the review is conducted by a person who understands the production and in-process control system, understands the significance of a processing deviation, and knows how to respond to a deviation. Such understanding and knowledge will ensure that the review is appropriately conducted, and that the response to any deviation is measured and appropriate.

Proposed § 106.6(c)(5) requires that infant formula manufacturers establish recordkeeping procedures, in accordance with proposed § 106.100(e)(3), that ensure that compliance with the requirements of proposed § 106.6(c) is documented. As discussed below in the description of the proposed revisions to subpart F of part 106, FDA has authority to require that these records be made and retained under section 412(b)(4)(A)(i) of the act. FDA is proposing to provide a complete description of all recordkeeping requirements in subpart F. When applicable, FDA is including cross-references to these recordkeeping requirements in the regulations in subparts B, C, and D. These records will allow manufacturers to discern trends or to pinpoint the onset of a problem if a standard or specification is not being met at a point where control is deemed necessary to prevent adulteration, or if a batch of infant formula is associated with an adverse event.

3. Controls to Prevent Adulteration by Workers

Proposed § 106.10(a) requires that there be sufficient personnel, qualified by training and experience, to perform all operations, including all required recordkeeping, in the manufacture, processing, packing, and holding of each infant formula and to supervise such operations to ensure that they are correctly and fully performed. Proposed § 106.10(a) is consistent with existing regulations concerning CGMP for foods (§ 110.10(c)) and drugs (§ 211.25). In this provision, FDA is proposing a general standard for determining how many employees are necessary, i.e., that there be enough to achieve, maintain, and document CGMP. However, FDA is leaving the determination of the actual number of employees necessary to the manufacturer's discretion.

Proposed § 106.10(a) also requires that such personnel be qualified by training and experience. Training is necessary to ensure that employees know how to correctly and fully perform the operations in question and to ensure that employees are competent to produce a safe and clean infant formula. The extent and frequency of training is left to the manufacturer's discretion.

Proposed § 106.10(b) requires that personnel working directly with infant formula, infant formula raw materials, infant formula packaging, or infant formula equipment or utensil contact surfaces practice good personal hygiene to protect the product against contamination. Proposed § 106.10(b) is consistent with existing regulations concerning CGMP for foods (§ 110.10(b)) and drugs (§ 211.28(a) and (b)). FDA has tentatively concluded that it is necessary that these employees practice good hygiene so that they will not transmit disease to others in the workforce, and so that they will not transmit filth or pathogenic microorganisms to the infant formula.

In addition, proposed § 106.10(b) enumerates the basic elements of good personal hygiene. Proposed § 106.10(b)(1) lists clean outer garments and protective apparel as one element. To be ''clean,'' clothing must be free of filth or microorganisms that may contaminate the infant formula. Protective apparel, such as head, face, hand, and arm coverings, will help to ensure that the infant formula is protected from contaminants such as hair.

Proposed § 106.10(b)(2) states that good personal hygiene includes workers washing their hands thoroughly in a hand washing facility with soap and running water at a suitable temperature before starting work, after each absence from the work station, and at any other time when hands may become soiled or contaminated. Filth and pathogenic microorganisms can be brought into the processing environment on the employee's hands from outside areas, restrooms, contaminated raw materials, waste or waste receptacles, and other insanitary objects (Refs. 10, 11, and 12). FDA has tentatively concluded that requiring workers to practice good personal hygiene by washing their hands at the times specified will help to prevent the introduction of this type of contamination into infant formula.

Proposed § 106.10(c) requires that any person who reports that he or she has, or appears by medical examination or supervisory observation to have, an illness, open lesion, including boils, sores, or infected wounds, or any other source of microbial contamination that creates a reasonable possibility that the safety of the formula may be adversely affected, be excluded from direct contact with ingredients, containers, closures, in-process materials, equipment, utensils, and infant formula product until the condition is corrected or determined by competent medical personnel not to jeopardize the safety of the infant formula. Proposed § 106.10(c) is consistent with existing regulations concerning CGMP for foods (§ 110.10(a)) and drugs (§ 211.28(d)). Employees can transmit the organisms responsible for diseases, such as salmonellosis, shigellosis, and hepatitis, to the infant formula. Additionally, open sores, boils, or infected wounds present the potential for contamination of the infant formula with such pathogenic microorganisms as *Staphylococcus aureus* (Refs. 14 and 15). Thus, proposed § 106.10(c) will exclude employees who carry potential microbial contamination that may adversely affect the safety of the formula from direct contact with the infant formula and from direct contact with materials and surfaces that come in contact with the infant formula and thus will minimize the potential for employees to transmit microorganisms to the infant formula that may cause the infant formula to pose a health hazard to the infant.

4. Controls to Prevent Adulteration Caused by Facilities

Proposed § 106.20(a) requires that buildings used in the manufacture, processing, packing, or holding of infant formula be maintained in a clean and sanitary condition. This proposed requirement is necessary to prevent contamination of the infant formula. It is consistent with FDA's existing regulations concerning CGMP for foods (§§ 110.20(b) and 110.35(a)) and drugs (§ 211.42). Trash, litter, and waste must be disposed of to avoid creating conditions that attract and harbor potentially pathogenic microorganisms and attract and harbor pests, such as rodents or insects. Such pests can carry a variety of human disease agents, including microorganisms that are potentially pathogenic in infants, and introduce them into the manufacturing environment (Refs. 10 and 12). They are also sources of feces and hair that can contaminate infant formula.

Proposed § 106.20(a) also requires that buildings used in the manufacture of infant formula have space for the separation of incompatible operations, such as the handling of raw materials, the manufacture of the product, and packaging and labeling operations. If raw materials are not separated from the site of product manufacture, there is a significant possibility that they will be used in infant formula manufacture before they have been tested and found acceptable for use in infant formula. Therefore, FDA has tentatively concluded that the separation of incompatible operations is necessary to ensure that infant formula is manufactured in a manner designed to prevent adulteration. The proposed requirement that incompatible operations be separated is consistent with FDA's existing regulations concerning CGMP for foods (§ 110.20(b)(2)) and drugs (§ 211.42(c)) and is consistent with the recommendations made to FDA by the Infant Formula Council (Ref. 9).

Proposed § 106.20(b) requires separate holding areas to protect against mixups that could lead to contamination of infant formula. Failure to separate raw materials or in-process materials that have not been released, or that have been rejected but not disposed of, from those that have been released creates the potential for the use of ingredients that do not meet the applicable specifications and thereby can lead to the production of finished infant formula that is adulterated. Similar types of problems can develop if final product that has not been released, or that has been rejected but not disposed of, is not separated from final product that has been released. Proposed § 106.20(b) is consistent with FDA's existing regulations concerning CGMP for drugs (§ 211.42(c)).

Proposed § 106.20(c) defines a standard for adequate lighting and allows the manufacturer to exercise discretion in determining the precise level of lighting that is sufficient to meet that standard. Adequate lighting is important. Inadequate lighting may make it difficult to read a label or an instrument, and as a result incorrect ingredients may be used in infant formula production, or instruments may be read incorrectly, which increases the risk of producing an adulterated infant formula.

Proposed § 106.20(c) also requires that any lighting fixtures directly over or adjacent to exposed raw materials, in-process materials, or bulk (unpackaged) finished product be protected to prevent glass from contaminating the product in the event of breakage. Glass in an infant formula may be a safety hazard and would render the formula adulterated (Ref. 14). Proposed § 106.20(c) is consistent with FDA's existing regulations concerning CGMP's for food (§ 110.20(b)(5)) and drugs (§ 211.44).

FDA is proposing a requirement in § 106.20(d) for air filtration systems to improve air quality in production areas

and thus reduce the potential for contamination by air-borne sources (Ref. 15). This proposed requirement is consistent with FDA's existing regulations concerning CGMP for drugs (§ 211.46(c)).

Proposed new requirements in § 106.20(e) protect against the contamination of infant formula by pest control agents and cleaning agents. The agency recognizes that these agents are needed in infant formula facilities. However, because many of them are toxic, they must be handled and stored in a manner that prevents contamination of the infant formula. Proposed § 106.20(e) is consistent with FDA's existing regulations concerning CGMP for food (§ 110.35(b)(2)) and drugs (§ 211.56(c)).

Proposed § 106.20(f)(1) states that potable water used in the manufacturer of infant formula must meet the Environmental Protection Agency's (EPA's) Primary Drinking Water Regulations (40 CFR part 141) (with the one exception that the fluoride level be as low as possible, as discussed below). This proposed regulation is consistent with FDA's existing regulations concerning CGMP for drugs (§ 211.48(a)).

The Safe Drinking Water Act gives EPA the responsibility for establishing standards for public drinking water. Therefore, FDA is proposing to use EPA's standards for water used in the production of infant formulas. Application of these standards will ensure that the water used in infant formula is safe. The agency is proposing to require that water from both municipal sources and the firm's own wells meet these standards.

The safety and sanitary quality of water from public water systems is generally ensured through public water treatment, chlorination, or monitoring and control by local health authorities. Private sources of water, however, particularly surface waters or water from shallow wells, may be subject to microbiological, chemical, or radiological contamination attributable to the source itself or to surface contamination at the well head or intake. Private sources are also frequently untreated or minimally treated. Thus, under the proposed regulation, when a manufacturer uses a private source of water, it will need to take steps to ensure that the water is safe and sanitary. These steps may include ensuring that the well design has been approved by the local health authority, ensuring that the well meets coliform test standards, performing periodic inspections of the sanitary condition of the well head and source intake, and performing and monitoring appropriate water treatment procedures, including filtration, sedimentation, and chlorination. The type and frequency of controls exercised by the manufacturer will be based upon the type of source water and its historic safety and sanitary quality.

Proposed § 106.20(f)(1) makes one exception to the use of EPA standards for drinking water. On April 2, 1986, EPA issued a maximum contaminant level (MCL) for fluoride in drinking water of 4 milligrams per liter (mg/L) (51 FR 11396) and reaffirmed this level on December 29, 1993 (58 FR 68826). The National Academy of Sciences (NAS) recommends 0.1 to 0.5 mg/day as the safe and adequate intake for infants from 0 to 6 months of age. Mottling of teeth in children has been observed at 2 to 8 milligrams/kilogram (mg/kg) concentration of fluoride in diet and drinking water (Ref. 16). Thus, if 4 mg of fluoride/L of water was allowed in the water used in infant formula manufacture, infants consuming ready-to-feed infant formula could receive enough fluoride to adversely affect their teeth. Currently, no infant formulas are manufactured with fluoridated water (Ref. 17), so that the pediatrician or other health care provider is able to decide whether a fluoride supplement is appropriate for formula-fed infants, principally by considering whether the formula was diluted with fluoridated water (Ref. 18).

NAS has established a safe and adequate daily dietary intake of fluoride for infants (Ref. 19). The agency is considering proposing to revise the infant formula nutrient requirements in § 107.100 to include fluoride and other nutrients that NAS has determined are essential for infants. FDA will consider fluoride levels for infant formulas at that time. FDA has tentatively concluded that, until it has revised the levels of required nutrients, manufacturers should continue their practice of not using fluoridated water in the manufacture of infant formula.

Proposed § 106.20(f)(1) also requires that the water be supplied under continuous positive pressure in a plumbing system that is free of defects that could contaminate an infant formula. FDA has tentatively concluded that this requirement is necessary to ensure that all potable water coming into the plant is not adversely affected by the in-plant plumbing. Contaminated water can serve as a vehicle for contamination of infant formula, both when used as an ingredient in the infant formula and when allowed to enter the product indirectly, as can occur, for example, when water is used to cool the product after retorting. Thus, FDA tentatively concludes that it is appropriate to include this positive requirement in this regulation.

Proposed § 106.20(f)(2), which sets forth requirements for testing representative samples of potable water used in infant formula manufacturing, is necessary to provide assurance that the water used in infant formula manufacturing meets EPA's standards. Proposed § 106.20(f)(3) requires that manufacturers conduct these tests with appropriate frequency. The regulation allows manufacturers some discretion in determining the testing frequency necessary to ensure that EPA standards are met, but it requires a minimum frequency of testing for certain contaminants (i.e., chemical contaminants, radiological contaminants, and bacteriological contaminants). FDA is basing these proposed minimum frequencies on those adopted by EPA for primary drinking water. This frequency of testing is consistent with FDA's own regulations concerning processing and bottling of bottled drinking water (§ 129.35(a)(3)).

Proposed § 106.20(f)(4) requires that manufacturers make and retain records of the frequency and the results of the testing that they do on the water used in the production of infant formula. These records will document that the manufacturer is complying with the potable water testing requirements of § 106.20(f)(2) and (f)(3), and that the water complies with EPA standards. They will identify any trend toward loss of compliance with these standards, so that the manufacturer can take corrective actions before the water becomes inappropriate for use in infant formula. As discussed below in the description of the proposed revisions to subpart F, FDA has authority to require the creation and retention of these records under section 412(b)(4)(A)(i) of the act.

In proposed § 106.20(g), FDA sets out requirements regarding piping systems to prevent a source of contamination (i.e., waste water) from coming in contact with the infant formula. Cross connections could allow back siphonage into a potable system from a nonpotable system under negative pressure conditions and thus could result in the chemical or microbiological contamination of the potable water system (Ref. 20). Proposed § 106.20(g) is consistent with FDA's regulations concerning CGMP for food (§ 110.37(b)(5)) and drugs (§ 211.48(b)).

Proposed § 106.20(h) requires that steam that comes in direct contact with infant formula be safe and free of rust

and other particulate matter that could contaminate the formula. Steam comes in direct contact with infant formula when the steam is injected into the head space of a can of infant formula to create a vacuum. Thus, this proposed requirement is necessary to ensure that the steam does not adulterate the infant formula.

Proposed § 106.20(h) also requires that boiler water additives in the steam meet safety standards set forth in FDA regulations at 21 CFR 173.310 which lists boiler water additives that may be safely used in the preparation of steam that will contact food and the conditions for the safe use of those boiler water additives. This proposed requirement is necessary because boiler water additives dissolve in water and can be carried over as a residue in the steam. A proposed requirement that boiler water additives in the steam comply with § 173.310 will ensure that any residue is safe to come in contact with the infant formula.

Proposed § 106.20(i) requires that each infant formula manufacturing site provide its employees with readily accessible toilet and hand washing facilities. This proposed requirement is consistent with good sanitary practice common to all food-processing facilities and is consistent with FDA's CGMP regulations for foods (§ 110.37(d) and (e)) and drugs (§ 211.52). The requirement is also a necessary adjunct to the requirement in proposed § 106.10(b)(2) that employees wash their hands before starting work, after each absence from the work station, and at any other time when the hands may become soiled or contaminated. Hand-washing facilities are not likely to be used in an appropriate manner by employees if the facilities are not conveniently located.

Proposed § 106.20(i) also requires that these facilities be equipped with hot and cold water, ordinary soap or detergent, and single-service towels to ensure that microbiological contamination does not occur through the repeated use of the same towel by several individuals.

In addition, proposed § 106.20(i) requires that toilet facilities be maintained in good repair and in a sanitary condition at all times, and that these facilities provide for proper disposal of sewage, so that the processing environment is protected against pathogenic microorganisms shed in fecal material. Restroom floors and the grounds around the processing facility can become contaminated with pathogens if fecal material is not removed by an adequate sewage system. Foot traffic over the affected areas can introduce pathogens into the processing room and cause product contamination. Insanitary toilet facilities can also increase the potential for contamination of employees' hands and, ultimately, of the product itself (Refs. 10 and 11). Proposed § 106.20(i) further protects against potential microbiological contamination by setting forth requirements for the positioning of toilet facility doors.

5. Controls to Prevent Adulteration Caused by Equipment or Utensils

Equipment used in infant formula manufacture, packaging, or holding that is of an inappropriate design or an inadequate size, or that is installed improperly, can result in a variety of problems. For example, a mixer for the blending of powdered ingredients will not properly perform its function if the blade is too small relative to the size of the mixer, or if the mixer blade or auger is not properly positioned in the inside of the mixer. Such a mixer may produce infant formula that is not uniform in composition throughout a batch and that is, consequently, adulterated because the required nutrients are not provided at the required levels throughout the batch.

Installing equipment in a manner that will facilitate its cleaning and maintenance is also important in preventing adulteration. Equipment that is not properly cleaned can be the source of contaminants that adulterate the infant formula. Equipment that is not properly maintained can result in a variety of problems. For example, improper maintenance of equipment such as a mixer may result in inadequate compositional uniformity in a batch of formula. Improper maintenance of equipment used to measure a parameter such as temperature may result in the processing of the infant formula at a temperature that can adversely affect the product. In either case, the product would be adulterated. Design and installation of equipment also needs to be checked when the equipment is modified or repaired to ensure that the equipment is still designed and installed to function as intended as part of the manufacturing process. Thus, proposed § 106.30(a) requires that equipment be appropriately designed and installed. This proposed requirement is consistent with FDA's CGMP regulations for foods (§ 110.40(a)) and drugs (§ 211.63).

If a food-contact surface is constructed of toxic material, the product may be directly contaminated with that material (Ref. 11). Therefore, FDA is proposing to require in § 106.30(b) that equipment and utensils be made of materials that are not reactive or absorptive, so that the equipment and utensil materials do not contaminate the infant formula and cause it to be adulterated. Proposed § 106.30(b) also requires that such equipment and utensils be designed to be easily cleanable because they can be vehicles for microbial contamination of both raw and finished products. Utensils, equipment, and other food-contact surfaces that are made of corrosive material, or that contain breaks, pits, cuts, or grooves, are difficult to clean because the pores and crevices shield the microorganisms from the action of cleaning and sanitizing agents (Ref. 21). In addition proposed § 106.30(b) requires that equipment and utensils be designed to withstand the environment in which they are used. This requirement will ensure that equipment and utensils are constructed of materials that will not corrode or undergo other types of chemical or physical degeneration resulting from their use in infant formula production. Degeneration of the equipment and utensils may introduce contaminants into the formula and thereby lead to adulteration. Surfaces that are not adequately cleaned and sanitized can be a source of filth, an attractant for vermin, and a reservoir for microorganisms.

Proposed § 106.30(b) requires regular, effective cleaning and sanitizing of all food-contact surfaces to minimize the probability of contamination of the infant formula (Ref. 21) and prescribes requirements for effective sanitizing agents. An effective sanitizing agent is one that has a good bactericidal effect on the types of microorganisms normally present in the plant environment and that is safe, stable, and convenient for use (Ref. 22). Sanitizing agents are indirect food additives and must be used in accordance with 21 CFR 178.1010, which prescribes their conditions of safe use. Examples of sanitizing agents that comply with § 178.1010 include hypochlorites, iodophors, and quaternary ammonium compounds. However, sanitizers can achieve their intended effect only if they are applied to a surface that has been thoroughly cleaned, and if they are applied at a proper concentration (Ref. 22).

Thus, it is important that effective cleaning compounds be used. An effective cleaning compound is one that will lower the surface tension of water so that spills can be lifted and flushed away (Ref. 23). Ordinary soap has a limited ability to solubilize fats, oils, and proteins, and inorganic alkaline

detergents can dissolve food solids such as fats and proteins, but mineral deposits will frequently require the use of acid cleaners (Ref. 23).

In order to ensure that infant formula is not contaminated with unsafe substances that are a part of the manufacturing process, FDA is proposing requirements in § 106.30(c) regarding substances necessary for the operation of equipment, such as lubricants or coolants.

Proposed § 106.30(d)(1) sets forth requirements for maintaining the accuracy of instruments, since an instrument that is not easily read, or that is not properly calibrated, may not provide accurate measurements. If an instrument is not properly maintained, it may not be reliable over time, and the readings obtained from it may lead to adulteration of the infant formula during processing. This proposed regulation also requires that such instruments be sufficient in number for their intended use. For example, if the temperature of a large piece of equipment needs to be monitored, several temperature-indicating devices may be needed to accurately monitor the temperature in all parts of the equipment. Also, instruments and controls must be tested for accuracy (i.e., calibrated) against a known reference standard before first use and at routine intervals thereafter, as specified in writing by the manufacturer of the instrument or control, or as otherwise deemed necessary to ensure the accuracy of the instrument. FDA has tentatively concluded that this requirement is necessary because equipment used to manufacture infant formula must operate properly to ensure production of a safe, uniform product with a consistent nutrient content throughout a lot or a batch.

The accuracy of an instrument is the degree to which it produces a correct result. The instruments used to measure parameters such as temperature or pressure at points where control is deemed necessary to prevent adulteration must reflect the true measurement so that, for example, a manufacturer can have confidence that when a thermometer indicates that the temperature is 240 °F, the temperature really is 240 °F. FDA's experience is that calibration of the instrument using a reference standard is the most reliable method to ensure accuracy. FDA is proposing to require that this test for accuracy be done before first use to provide assurance that the instruments and controls will perform as intended and at routine intervals afterward to ensure that the instruments and controls continue to perform as intended.

Reliability is the instrument's accuracy over time. The reliability of the instrument will determine the length of time that it can be used before it begins to lose accuracy. The manufacturer of the instrument is in the best position to establish how frequently recalibration is needed because that manufacturer is responsible for putting together the technology by which the instrument operates. However, if the infant formula manufacturer's experience with the instrument demonstrates that the instrument needs to be calibrated more frequently than the instrument manufacturer suggests, FDA has tentatively concluded that the infant formula manufacturer must act on its own experience with the instrument and calibrate it as often as necessary to ensure the accuracy of the instrument.

Proposed § 106.30(d)(1) further requires that the known reference standard be certified for accuracy at routine intervals specified in writing by the manufacturer of the instrument, or as otherwise deemed necessary. Known reference standard devices are accompanied by certificates of accuracy, but these certificates do not preclude the possibility that these instruments will go out of calibration. Just as a calibration routine needs to be established for the process instrumentation, a recertification of the known reference standard needs to be established in accordance with the equipment manufacturer's recommendations. For example, the length of time that a certified thermometer can be considered reliable will depend on the materials used in its manufacture, the degree of control exercised in its manufacture, and its use, as would be the case for the indicating thermometer used in the production line. The accuracy of a calibrated thermometer is only going to be as good as the accuracy of the known reference standard that is used during its calibration.

Proposed § 106.30(d)(1) also requires that manufacturers make and retain records of accuracy checks in accordance with the provisions of proposed § 106.100(f)(2). As discussed below in the description of the proposed revisions to subpart F of part 106, FDA has authority to require these records under section 412(b)(4)(A)(i) of the act. These records will enable the manufacturer to establish the historical performance of the instrument to determine whether the calibration schedule is sufficient to ensure the accuracy of the instrument and will provide information on when and how the instruments were calibrated to assist the manufacturer in identifying the cause of a problem that may arise with a batch of infant formula.

Proposed § 106.30(d)(2) requires that instruments and controls that cannot be adjusted to agree with the reference standard be repaired or replaced. FDA is proposing this requirement because an instrument or control cannot be trusted for use in infant formula production if it cannot be adjusted to agree with the reference standard. Adjustments made to reach agreement with a known accurate or reference standard must also be done in accordance with any adjustment range limitations specified by the vender of the instrument.

Proposed § 106.30(d)(3) provides that if calibration of an instrument (testing for accuracy against a known reference standard) shows that a specification or standard has not been met at a point where control is deemed necessary to prevent adulteration, a written evaluation must be made of all affected product and of any actions that need to be taken. FDA has tentatively concluded that this written evaluation is necessary because if an instrument has been giving inaccurate readings, all infant formula produced subject to such inaccuracies must be identified and evaluated for the possibility that the inaccuracies resulted in the production of adulterated formula. If the manufacturer determines that adulterated formula has been produced, the firm must decide what actions, if any, need to be taken to prevent such formula from reaching infants.

FDA is also requiring that this written evaluation needs to be maintained in the firm's records. FDA tentatively concludes that this record is necessary to demonstrate that the firm has complied with CGMP. As discussed below in the description of the proposed revisions to subpart F of part 106, FDA has authority to require that these records be retained under section 412(b)(4)(A)(i) of the act.

Proposed § 106.30(e)(1) requires that the temperature in cold storage compartments used to store raw materials, in-process materials, or final product, as well as the temperature of thermal processing equipment used at points where temperature control is necessary to prevent adulteration, be monitored with such frequency as is necessary to ensure that temperature control is maintained. The frequency of the monitoring is left to the manufacturer to determine. Growth of microorganisms can occur and cause spoilage if materials that should be kept in cold storage compartments are not maintained at the proper temperature. Infant formula may also be adulterated if thermal processing equipment is not

operated at the proper temperature, and the final liquid infant formula product is not commercially sterile. Therefore, FDA tentatively concludes that their requirement is appropriate.

In addition, FDA is proposing that a temperature of 40 °F (4.4 °C) is appropriate in cold storage compartments to minimize the growth of pathogens (Ref. 24) and the deterioration of liquid ingredients, nutrients, and the formulated product before canning (proposed § 106.30(e)(2)).

Proposed § 106.30(e)(3)(i) requires that cold storage compartments and thermal processing equipment be equipped with easily readable, accurate temperature-indicating devices. These devices are necessary to ensure that the manufacturer can monitor the temperatures where materials are stored or where product is processed. Proposed § 106.30(e)(3)(ii) requires that thermal processing equipment be equipped with temperature-recording devices that reflect the true temperature on a continuing basis, so that the manufacturer will be able to determine whether the product was thermally processed at a minimum temperature for an appropriate period of time. Two factors, temperature and time, are relevant in ensuring that thermal processing is conducted in a manner that will produce commercially sterile infant formula after retorting. Thus, recording the temperature that is maintained during the time period used will show whether the thermal process is conducted properly.

Proposed § 106.30(e)(3)(ii) also requires that cold storage compartments be equipped with either a temperature-recording device that will reflect the true temperature within the compartment on a continuing basis, or a high-temperature alarm or a maximum-indicating thermometer that has been verified to function properly. These temperature records will show whether the materials were stored at an appropriate temperature to minimize the growth of pathogens and the deterioration of ingredients and formulated product. If the manufacturer does not wish to equip cold storage compartments with such temperature-recording devices, FDA is proposing to require that it maintain a temperature log in which the temperature in the compartment is noted with such frequency as is necessary to achieve control. The agency is leaving it to the manufacturer's discretion to determine what frequency of temperature notation is necessary to achieve control.

The agency has tentatively concluded that it is not necessary for the manufacturer to record the temperature of the cold storage compartment on a continuous basis as long as the manufacturer can determine that the temperature of the cold storage compartment has gone above 40 °F. A high-temperature alarm set to go off when the cold storage compartment goes above 40 °F will allow the manufacturer to make this determination. Likewise, a maximum-indicating thermometer will remain at the highest temperature that it ever reaches. If the maximum indicating thermometer indicates a temperature above 40 °F, the infant formula manufacturer must assume that the temperature has been above 40 °F since the last check of the thermometer. Thus, FDA has tentatively concluded that either a high-temperature alarm or a maximum-indicating thermometer are acceptable alternatives for determining whether the cold storage compartment has gone above 40 °F.

In some cases, the actual location of the sensors may be an important factor in ensuring the accurate representation of temperature. For example, one sensor located at the end of a large piece of thermal processing equipment may not accurately represent the temperature in the whole piece of equipment. In addition, these temperature devices must often be read under less than ideal plant conditions, so they should be installed in a location that facilitates easy reading. Temperature-recording devices can be easily jarred and rendered inaccurate. They can be recalibrated against a reference temperature-indicating device (e.g., a thermometer) quite easily, however. Manufacturers should do so at least at the beginning and end of each production day in order to determine whether the instrument was accurate throughout the day's production. For thermal processing equipment used to produce commercially sterile liquid infant formula, the mandatory and recommended procedures of 21 CFR part 113 apply.

FDA is also proposing that manufacturers make and retain records, in accordance with the provisions of proposed § 106.100(f)(3), of the temperatures indicated or recorded by these devices (see § 106.30(e)(3)). As discussed below in the description of the proposed revisions to subpart F of part 106, FDA has authority to require these records under section 412(b)(4)(A)(i) of the act. They are needed to show that the thermal processing equipment or cold storage compartments are being maintained at the correct temperatures to prevent adulteration of the product. They also will enable the manufacturer to identify trends in temperature fluctuations that can signal the need to perform nonscheduled maintenance.

Proposed § 106.30(e)(4) requires that for thermal processing, the temperature-recording device not read higher than the calibrated temperature-indicating device because it is important to ensure that the infant formula is processed at a minimum temperature for a continual period of time. A temperature-recording device reading higher than the reference temperature-indicating device for thermal processing equipment would show that the product had been processed at a temperature higher than the true processing temperature. Because thermal processing is used to destroy microorganisms, a temperature-recording device reading higher than the true processing temperature may mean that the product has not been processed at a temperature that is high enough to destroy all microorganisms.

For cold storage compartments, the temperature-recording device must not read lower than the temperature-indicating device because when raw materials, in-process materials, or finished product must be stored at a cold temperature, it is important to ensure that the infant formula was not exposed to a temperature above the maximum temperature. A temperature-recording device reading lower than the reference temperature-indicating device for cold storage equipment would show the materials in the compartment as having been held at a lower temperature than the true temperature. Because cold storage is used to prevent microbiological growth, a temperature-recording device reading lower than the reference temperature-indicating device would mean that the material was actually being stored at a higher temperature than the recorded temperature, and that, as a result, microbial growth may have occurred.

Proposed § 106.30(f) requires that all equipment and utensils used in the manufacture of infant formula be cleaned, sanitized, and maintained at regular intervals to prevent adulteration of the infant formula. Any equipment or utensil that is not cleaned and maintained properly can be a source of contamination. FDA is therefore proposing to require that cleaning, sanitizing, and maintaining be done at regular intervals. The details of sanitation procedures e.g., equipment cleaning, can differ from plant to plant depending upon the type of operation and other conditions. In one plant, it may be necessary to disassemble all or part of the equipment to clean it. In other plants, breaking down the

equipment may not be necessary. Likewise, different cleaning compounds may be needed from one plant to another to solve specialized problems such as buildups of mineral deposits. Each manufacturer should study its own plant and develop a procedure that is tailored to that plant's needs and circumstances.

FDA considers that cleaning, sanitizing, and maintaining equipment and utensils is so important for ensuring that adulterated infant formula is not produced that it is proposing to require that the cleaning, sanitizing, and maintenance be checked for satisfactory completion by an individual qualified to conduct such a review. Such an individual will understand the importance of ensuring that cleaning, sanitizing, and maintenance is properly done, so that equipment and utensils do not contribute to the adulteration of the infant formula. Also, the agency has tentatively concluded that this requirement will ensure that there is accountability for proper performance of this function.

In addition, proposed § 106.30(f) requires that manufacturers make and retain records on equipment cleaning, sanitizing, and maintenance in accordance with proposed § 106.100(f)(4). As discussed below in the description of the proposed revisions to subpart F, FDA has authority to require these records under section 412(b)(4)(A)(i) of the act. These records will document when the cleaning, sanitizing, and maintenance of equipment occurs and will allow the manufacturer to trace all formula that may be affected if cleaning, sanitizing, or maintenance is not properly performed.

In order to ensure that compressed air or other gases will not contaminate the infant formula with unlawful indirect food additives or other chemical, physical, or microbiological contaminants, FDA is proposing to require in § 106.30(g) that they be appropriately treated. Air or other gases that are not properly treated and filtered, or air that is not of the proper purity, can introduce contaminants into the infant formula that may render it adulterated. Also, compressed gases can be contaminated with oil from the compressor or with filth or microbiological contaminants from the compression, storage, or distribution equipment. Filtration at the air intake and after compression, storage, and distribution is an effective means of reducing the risk that such contaminants will enter the gases and, thereby, the food. Therefore, FDA is also proposing in § 106.30(g) to require the use of a filter when compressed gases are used at product filling machines to replace air removed from the headspace of containers. The filter will prevent contaminants from entering the infant formula during that operation (Ref. 25).

6. Controls to Prevent Adulteration Due to Automatic (Mechanical or Electronic) Equipment

Manufacturers of infant formula are increasingly relying on automatic equipment (including mechanical and electronic equipment) in production and quality control. In some cases, manufacturers are replacing manually initiated processing procedures with automated process control systems to ensure proper formulation (addition of ingredients and premixes), mixing, or processing of an infant formula or to test a batch of infant formula. Such automated process control systems frequently consist of a computer or system of computers that controls many or all stages of production, in-process sampling, and testing. In other cases, manufacturers are relying on programmable equipment (such as an autoanalyzer) to perform a critical function, such as testing a batch of infant formula to ensure that the batch meets the nutrient requirements of the act. In all cases, it is important that such systems and equipment function as expected to ensure that the infant formula contains the required nutrients at the required levels and is manufactured according to the CGMP and quality control procedures prescribed under section 412(b)(2) of the act and therefore is not adulterated under section 412(a)(1) or (a)(3) of the act.

FDA is proposing to define ''hardware,'' ''software,'' ''system,'' and ''validation'' in § 106.35 because the use of these terms will simplify the language of the proposed regulations and will clarify which sections of the proposed regulations apply to hardware only, to software only, or to systems consisting of both hardware and software.

The definition of ''hardware'' in proposed § 106.35(a)(1) is based on common usage of the term and makes clear that the regulations in proposed § 106.35 apply to all automatic equipment, whether the equipment is mechanical or electronic in nature. Proposed § 106.35(a)(1) also makes clear that electronic equipment includes, but is not limited to, computers. This definition of ''hardware'' distinguishes those elements of equipment that have a physical form from the elements considered to be intellectual property that may be encoded on a physical element such as a diskette, tape, or microprocessing chip.

Software may be developed by an infant formula manufacturer, by a manufacturer of equipment purchased by the infant formula manufacturer, or by a third party vendor (such as the vendor of a computer operating system). The definition of ''software'' in proposed § 106.35(a)(2) derives from the ISO International Guideline ISO–9000–3[1] (Ref. 26) and the Institute for Electrical and Electronics Engineers, Inc. (IEEE) Standard 610–12–1990[2] (Ref. 27) and is consistent with the definition of software in FDA's ''Glossary of Computerized Systems and Software Development Terminology (Ref. 28). FDA is proposing to incorporate this definition into the agency's infant formula regulations because the definition is derived from internationally accepted definitions, includes documentation, applies to the operation of all types of hardware (rather than the narrowly defined ''data processing system'' or ''computer system'' included in the definitions from the ISO and IEEE, respectively), and is consistent with current FDA terminology. Software documentation consists of the instructions on how to use the software. FDA has tentatively concluded that such instructions need to be included in the definition of ''software'' to ensure the proper operation of the software.

The definition of ''system'' in proposed § 106.35(a)(3) derives from the IEEE Standard 610.12–1990 (Ref. 27). FDA is proposing to incorporate this definition because many of the requirements in proposed § 106.35 cannot be related to software or hardware alone but rather to systems in which software is used in conjunction with hardware. For example, testing software under simulated conditions of use may be beneficial during the early and middle stages of software development, but validation of the software must be performed in conjunction with the relevant hardware in the operational environment it is

[1] ISO is a world-wide federation of national standards bodies that set quality assurance guidelines for products that will enter international commerce. The ISO defines software as an ''intellectual creation comprising the programs, procedures, rules and any associated documentation pertaining to the operation of a data processing system'' (Ref. 26).

[2] IEEE is a trade organization comprised of several societies. IEEE standards are developed within the technical committees of the IEEE societies and represent a consensus opinion of experts from within IEEE as well as experts who are not members of IEEE. IEEE defines software as ''computer programs, procedures, and possibly associated documentation and data pertaining to the operation of a computer system'' (Ref. 27).

intended to be used in. Therefore in proposed § 106.35(b)(4), FDA is proposing that all systems be validated ''before their first use to manufacture commercial product.''

Proposed § 106.35(a)(4) defines ''validation'' as establishing documented evidence that provides a high degree of assurance that a system will consistently produce a product meeting its predetermined specifications and quality characteristics. It is important that a process control system comply with specified requirements each time it operates. The proposed definition is derived from the ISO International Guideline ISO–9000–3, (which defines ''validation'' as ''the process of evaluating software to ensure compliance with specified requirements'' (Ref. 26)); the IEEE Standard 610.12–1990, which (defines it as ''the process of evaluating a system or component during or at the end of the development process to determine whether it satisfies specified requirements'' (Ref. 27)); and FDA's ''Glossary of Computerized System and Software Development Terminology,'' which defines it as ''establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality characteristics'' (Ref. 28). FDA is proposing to incorporate these definitions into its regulations because they are applicable to the types of systems used in infant formula manufacture, are derived from internationally accepted definitions, are consistent with existing FDA terminology, make clear that the process of evaluation includes the complete system (i.e., the hardware used in conjunction with the software), and include the concept of consistency.

Proposed § 106.35(b)(1) sets forth requirements for designing, installing, testing, and maintaining all systems so that they function as intended. Some systems may work properly only within a narrow range of environmental conditions, such as temperature and humidity, and some might be particularly sensitive to electromagnetic interference. The actual conditions of use of a system should be considered as early as possible in its design and development. Systems need to be installed in a manner that takes into account the inherent limitations of the system, tested under conditions that reflect actual conditions of use, and properly maintained to ensure that they continue to function as expected during their lifetime.

Proposed § 106.35(b)(2) requires that the manufacturer ensure that all hardware is routinely calibrated, inspected, and checked according to written procedures. FDA has tentatively concluded that this provision is necessary to ensure that any infant formula manufactured under the control of automatic equipment meets the requirements of the act and is manufactured in a manner designed to prevent adulteration. For example, a batch of infant formula may lack the required levels of nutrients if equipment used for the automatic dispensing of a nutrient premix is out of calibration or has a clogged delivery line. The routine calibration, inspection, and checking of hardware will ensure that it continues to perform as intended, and that its operation will not result in a process that deviates from established specifications. The establishment of written procedures for the calibration, inspection, and checking of hardware will ensure that these procedures are performed consistently and in an appropriate way.

The incorporation of software into the operation of automatic equipment has not only increased the complexity of such equipment but also has resulted in a process that may operate differently for each execution because a software-based control system can be configured at will by the operator or by the system itself. Therefore, proposed § 106.35(b)(3), (b)(4), and (b)(5) require that manufacturers exercise appropriate controls over systems and, in particular, over the software used in the systems.

Proposed § 106.35(b)(3) prescribes procedures for ensuring that systems are checked for input and output errors resulting from faulty data entry, faulty programming, or equipment malfunction. Such errors can result in serious production or quality control errors leading to a contaminated or adulterated infant formula. For example, a faulty position sensor on a downstream valve that improperly indicates that it is closed may result in a post-sterilization contamination. An improperly installed (or empty) ink cartridge in a color printer or multi-pen recorder may cause portions of a record to not be printed. FDA has tentatively concluded that the regulation is necessary to ensure that the infant formula produced or analyzed using the system is not adulterated. However, proposed § 106.35(b)(3) also provides that the degree and frequency of input/output checks are to be based on the complexity and reliability of the system and the level of risk associated with the safe operation of the system.

Proposed § 106.35(b)(4) requires that manufacturers ensure that all systems are validated before their first use to manufacture commercial product. FDA has tentatively concluded that it is necessary that software programs that are used in a process control system to monitor and control established points deemed necessary to prevent adulteration (such as the speed of a pump, temperature of a heat exchanger, addition of vital nutrients, and air overpressure in an aseptic storage tank) be validated to ensure that use of the process control system will produce compliance with the specifications or standards at each control point. For example, if a continuous flow process is designed to heat an in-process batch of infant formula in a plate-to-plate heat exchanger to a specification of 271 °F, as indicated by the temperature at the end of the hold tube, and the system is mistakenly programmed to divert the product to the raw (unsterilized) surge tank only if the temperature drops below 261 °F, an in-process batch of infant formula heated to 261 °F would not be diverted to the raw surge tank but rather would be handled by the computer as if it were adequately processed. Such an underprocessed batch of infant formula would likely pose a foodborne biological hazard. Thus, FDA has tentatively concluded that the validation required under proposed § 106.35(b)(4) is necessary to ensure that infant formula that is produced or analyzed using the system is not adulterated.

The validation of software ordinarily includes the following elements: Requirements development, design, coding, debugging, testing (with the hardware), and maintenance (Refs. 29, 30, and 31). Software validation also includes a review for correctness of the software documentation to ensure that the instructions prompt the input of the proper commands or data by the user. However, depending on the nature of the software and the hardware that it controls, some or all of these aspects of the validation process may be done by the infant formula manufacturer, by the manufacturer of equipment that is purchased by the infant formula manufacturer, or by a third party vendor.

Proposed § 106.35(b)(4) leaves the identity of the person that does the validation to the discretion of the infant formula manufacturer but makes clear that the infant formula manufacturer is responsible for ensuring that the system is validated. The proposal does not stipulate any standards or specifications for the validation process because the extent of the validation necessary is

related to the level of risk that each component of the system presents.

More emphasis should be placed on validating portions of the system that represent major risk than on those that confer moderate or minor risk. A major risk is associated with systems that control or monitor a point where such control or monitoring is deemed necessary to prevent adulteration of the infant formula; for example, systems that control or monitor nutrient addition or processing temperature present a major risk. A moderate risk is associated with systems that influence, but that do not control or monitor, a point where control or monitoring is deemed necessary to prevent adulteration of the infant formula. For example, the speed of computer processing presents a moderate risk if software that is designed to be used on a high-speed computer is used on a slower computer. A minor risk is associated with systems that do not involve a point where control or monitoring is deemed necessary to prevent adulteration. For example, systems that control pallet stacking or product conveying present a low risk.

Proposed § 106.35(b)(5) requires that any system that is modified be revalidated after any modification and before use of the modified system to manufacture commercial product. FDA has tentatively concluded that revalidation is necessary to ensure that no errors are introduced into the system during the modification and to ensure that a modification in one aspect of a process control system does not, unknowingly but adversely, affect other aspects of the process control system, particularly those operations that follow the modified aspect of the system.

Under § 106.35(b)(5), FDA is also proposing that a specific individual (or group of individuals) is designated to modify software to prevent the indiscriminate modification of software and to ensure that all modifications are made consistently. The designated individual may be employed by the infant formula manufacturer, the manufacturer of equipment purchased by the infant formula manufacturer, or by a third party. The regulation states, however, that the infant formula manufacturer is responsible for ensuring that modified software is retested or revalidated regardless of who does the modification.

Proposed § 106.35(c)requires that infant formula manufacturers make and retain records concerning automatic (mechanical or electronic) equipment. FDA is proposing this requirement under the authority of section 412(b)(4)(A)(i) of the act, which requires the retention of all records necessary to demonstrate compliance with the CGMP and quality control procedures prescribed under section 412(b)(2) of the act, including the results of all testing required under section 412(b)(2)(B) of the act. These records will allow manufacturers to readily determine whether this crucial equipment is being appropriately operated and maintained. They will allow manufacturers to troubleshoot and to operate these systems with a minimum of downtime when problems occur because the records will include a copy of all software used and a backup file of data entered into the computer or related system which can be used to reload the system. The records will also provide information that the manufacturer can use in trying to determine why a problem with the system is occurring or why the system is not producing an infant formula that complies with the manufacturer's specifications for the product.

7. Controls to Prevent Adulteration Caused by Ingredients, Containers, and Closures

Proposed § 106.40(a) specifies that the only substances that may be used in infant formulas are food ingredients that are generally recognized as safe (GRAS) for use in infant formula, that are used in accordance with the agency's food additive regulations, or that are authorized by a prior sanction issued by FDA. Under section 412(b)(2)(A) of the act, FDA is to establish CGMP's that it determines are necessary to ensure that the infant formula is manufactured in a way that is designed to prevent adulteration of the formula. Unless the safety of the ingredients of an infant formula has been established, the formula is adulterated under section 402(a)(1) and (a)(2)(C) of the act. Thus, the agency has tentatively concluded that CGMP requires that the manufacturer ensure that the ingredients that it uses in its formula are safe and suitable.

Proposed § 106.40(b) requires that infant formula containers and closures not be reactive or absorptive so as to affect the safety of the infant formula, and that all packaging material that comes in contact with an infant formula be composed of authorized substances and be used in accordance with any prescribed limitations. Various regulations that authorize the use of a material in contact with the food product also set conditions and limitations on that use. Thus, the agency proposes to require that the manufacturer not only use only materials specified in proposed § 106.40(b), but also that the materials be used as specified in the regulations authorizing their use. This provision will ensure that the food contact surface of containers and closures will not adulterate the infant formula.

In order for the manufacturer to maintain a complete record of how each ingredient, container, or closure was used and to determine which lots of infant formula are adulterated if a problem is ultimately identified with a particular lot of ingredients, containers, or closures, FDA is proposing, in § 106.40(c), that they be identified with batch or lot numbers. This batch or lot number can be used to identify ingredients, containers, or closures that have been released for use in infant formula or rejected for use in infant formula manufacture. It also can be used to track the ingredients, containers, or closures that were used in the manufacture of each batch of infant formula.

Proposed § 106.40(d) requires that infant formula manufacturers develop written specifications that stipulate the standards for acceptance or rejection of ingredients, containers, and closures. Stipulating the standards for acceptance or rejection of ingredients used to supply nutrients is important to ensure that all the required nutrients are present in the formula at the required levels. For example, the level of endogenous nutrients that a manufacturer expects will be supplied by an ingredient should be stipulated as a standard for acceptance or rejection of that ingredient. Endogenous nutrients are nutrients provided as a part of other nutrients, such as minerals provided as a part of the protein source. Sodium, for example, is frequently provided as part of the protein ingredient ''caseinate.''

To ensure that the mineral is provided in the infant formula at at least the minimal level, and not above the maximum level, required by § 107.100, the infant formula manufacturer must know what amount of a mineral is provided to the formula by all ingredients that are sources of the mineral. Thus, a standard for the level of the endogenous nutrient that is to be provided by an ingredient is an appropriate specification for the manufacturer to develop. If the level of the mineral is too high in the ingredient, it may cause the formula to exceed the maximum established in § 107.100. Similarly, if the level is too low, the formula may not meet the required minimal level.

Developing standards for acceptance or rejection of ingredients used in infant formula manufacture is also important to ensure that contaminants in the

ingredients that may lead to adulteration of the product are not present in the formula. Examples of contaminants that may lead to adulteration of an infant formula include certain heavy metals, such as lead. Infant formula manufacturers are currently setting standards for the lead in the ingredients that they use in infant formula to ensure that the lead level in infant formulas is at or below the quantification limit of the method used for lead determination (Ref. 32).

Stipulating the standards for acceptance or rejection of containers or closures used in infant formula manufacture is important to ensure that the integrity of the container and of the closure is maintained to prevent leakage of the formula and to prevent an infant formula from becoming adulterated, which can occur if the container or closure is not impenetrable to air (which can cause nutrient degradation), or if the container or closure allows outside contaminants to get into the infant formula.

Proposed § 106.40(d) also requires that manufacturers establish written specifications that stipulate the procedures for determining whether the ingredients, containers, and closures meet the standards. Examples of procedures manufacturers may use to determine whether they meet the standards are acceptance of a supplier's guarantee or certification and testing conducted by the infant formula manufacturer. In some cases, manufacturers must conduct their own testing to ensure that the standards for acceptance or rejection of the ingredient are met. For example, section 412(b)(3)(B) of the act requires that manufacturers test each nutrient premix for each relied-upon nutrient to ensure that the premix complies with its specifications or certifications by a premix supplier, but the act does not require testing of individual nutrient ingredients when such nutrients are not supplied as a nutrient premix. However, a manufacturer may find through experience that the best way to ensure that the final product will meet all specifications is to test certain nutrient ingredients for identity, purity, and potency before using them in the infant formula.

In addition, manufacturers should have controls in place to ensure that any ingredients, containers, or closures that do not meet any of their specifications are not used in production of a batch of infant formula. However, if these controls fail, and any such ingredients, containers, or closures are used in a batch of formula, FDA is proposing under § 106.40(d) that an individual qualified by training or experience conduct an investigation to ensure that the failure does not lead to release into the marketplace of an adulterated product.

Proposed § 106.40(e) requires that ingredients, containers, and closures be stored in areas clearly designated for materials pending release for use, materials released for use, or materials rejected for use in infant formula production in order to prevent mixups in using materials that are inappropriate for infant formula manufacturing. FDA is further proposing to require that any lot of ingredients, containers, or closures that does not meet the manufacturer's specifications be rejected and controlled under a quarantine system designed to prevent its use in the manufacture of infant formula. Failure to protect against the use of these materials would significantly increase the likelihood that an adulterated product will be produced.

Some ingredients used in infant formula are vulnerable to degradation when they are exposed to heat or air. Moreover, containers or closures may be exposed to air containing dust and dirt and become contaminated. Thus, the ingredients, containers, and closures may need to be reexamined after they are exposed to air, heat, or other conditions that may adversely affect them to ensure that they still meet the manufacturer's specifications. Thus, FDA is proposing, in § 106.40(f), to require retesting or reexamination after approved materials have been exposed to conditions that may adversely affect them.

Proposed § 106.40(g) requires that manufacturers make and retain records on ingredients, containers, and closures used in the manufacture of infant formula so that if adulteration of formula occurs, the manufacturer will be able to determine the source of the material, so that its use can be halted. In addition, the records will show the basis on which each ingredient, container, and closure was released for use in infant formula production, if questions about such release later arise. FDA has authority to require these records, under section 412(b)(4)(A)(i) of the act.

8. Controls to Prevent Adulteration During Manufacturing

The infant formula manufacturing process involves a number of complicated processes that may cause adulterated formula to be produced if the processes are not properly conducted or monitored. Therefore, FDA is proposing, under section § 106.50, to require that manufacturers establish controls to minimize the risk that manufacturing process errors will produce an adulterated or unsafe formula. The proposed requirements reflect many of the practices currently used by infant formula manufacturers and manufacturers of other commodities that require strict production controls to prevent product adulteration (e.g., Ref. 9 and 21 CFR 211.100 through 211.115).

Proposed § 106.50(a)(1) carries forward and amends the requirement in current § 106.25(a) that a master manufacturing order be prepared and followed. A master manufacturing order is necessary to ensure that the manufacturer will produce each batch of a particular infant formula the same way. If the master manufacturing order is not followed, all necessary ingredients may not be added to the formula in the appropriate concentrations and in the appropriate manner.

FDA is also proposing that manufacturers make and retain records that include complete information relating to the production and control of the batch at the time each manufacturing operation is performed (see proposed § 106.50(a)(2)). This proposed requirement will ensure that the complete history of each batch of infant formula is available for review in the event that a problem arises with a particular batch.

Proposed § 106.50(a)(2) also requires that an individual qualified by training or experience conduct an investigation of any deviations from the master manufacturing order and any corrective actions taken. This investigation is necessary to ensure that any deviations from the master manufacturing order do not lead to an adulterated product.

If any changes are made to the master manufacturing order, proposed § 106.50(a)(3) requires that they be drafted, reviewed, and approved by a responsible official and include an evaluation of the effect of the change on the nutrient content and the suitability of the formula for infants. This process is necessary to prevent unintended adverse effects that could result from changes to the master manufacturing order made by persons not qualified to assess their impact. The production of infant formula is a sophisticated process, and all organizational units that are involved in critical formulation and production steps, such as production, engineering, research, and regulatory affairs, should review and approve changes to the master manufacturing order. FDA has tentatively concluded, however, that all changes to the master manufacturing order need to be

reviewed by at least one responsible official, and that this official will need to evaluate how the change will affect the nutrient content and the suitability of the product for infants, to ensure that the infant formula is not adulterated.

A significant change in the master manufacturing order without proper approval may result in the production of an infant formula that lacks a required nutrient or that is not manufactured in an appropriate way. For example, homogenization of an infant formula is done to ensure a uniform dispersion throughout the formula of the lipid ingredients as well as the fat-soluble nutrients. If the master manufacturing order were changed, and the homogenization process done before the fat source was added, the fat-soluble nutrients would not be uniformly dispersed in the formula, and the formula would be adulterated. The system of review and approval required by proposed § 106.50(a)(3) will minimize the possibility that a significant change could result in an adulterated product.

In order to ensure that the appropriate ingredients are added during the manufacturing process, and that the formula contains all of the nutrients required by § 107.100 and therefore is not adulterated, FDA is proposing in § 106.50(b) that each raw or in-process ingredient required by the master manufacturing order be examined by one person and checked by a second person or system. This requirement will ensure that there will be a check to prevent mixups in the use of ingredients and to prevent the use of unapproved ingredients. Confirmation that the master manufacturing order is being followed, and that ingredients are being properly added, is particularly important because these matters are fundamental to ensuring that the formula is manufactured correctly, and that it contains the nutrients required by § 107.100 but not unapproved ingredients that might adulterate the formula.

In proposed § 106.50(c), FDA is requiring the identification of all compounding and storage containers, processing lines, and major equipment used during the production of a batch of infant formula. Identification of these items will enable the manufacturer to accurately determine the status of all batches of infant formula during all stages of the manufacturing process, will help to prevent mixups in the addition of ingredients to the formula, and will facilitate prompt action by the manufacturer if any problems in processing are identified. For example, identifying that a particular storage container contains a batch of formula that has not yet had all ingredients added to it will prevent a manufacturer from inadvertently final-stage packaging the product and thus will help to ensure that adulterated product is not introduced into interstate commerce. The presence of the lot or batch number will help to identify the product if a problem does occur.

Proposed § 106.50(d) requires that manufacturers establish controls to ensure that required nutrient levels are maintained in the formula, and that the formula is not contaminated with microorganisms or other contaminants and thereby adulterated. In addition, the agency is proposing to require establishment of controls for mixing time, speed, temperature, and flow rate of product and other critical parameters necessary to ensure the addition of required ingredients to, and the homogeneity of, the formula. These parameters are determined by the manufacturer according to its experience and knowledge of what will result in a homogeneous, safe, and uniform product. It is essential that controls be established for each of these parameters, or the likelihood that there will be inconsistencies in production from batch to batch will be greatly increased. For example, if processing temperatures are not specified, the formula could be processed at high temperatures that can destroy vitamins or other essential nutrients, resulting in a product that is adulterated because it does not meet the nutrient requirements specified in section 412(i) of the act. Similarly, without established procedures for mixing time and speed, the product may be produced using processing parameters that will not result in formula that is uniformly mixed and thus does not contain all nutrients at the required levels.

FDA is proposing to require that manufacturers establish controls for the spray-drying process for powdered infant formula to prevent microbial and other contamination (§ 106.50(d)(2)). Although spray drying involves a heat treatment, the temperature is not sufficient to sterilize the formula. Consequently, powdered infant formulas are vulnerable to microbial contamination during the spray-drying process. Even if the equipment and the formula are free of microbial and other forms of contamination initially, the spray-drying process may permit contamination of the product as a result of dust or other air-borne gross particulates in the intake air. Thus, FDA has tentatively concluded that it is important that the manufacturer establish controls for the spray-drying process that will ensure that the powdered formula does not become contaminated with microorganisms or other contaminants.

The controls that manufacturers should consider include: (1) Using equipment constructed to ensure that static accumulation of particulate matter is controlled; (2) using and maintaining equipment constructed to protect the product from dust and environmental contamination; (3) controlling condensation, moisture, and temperature conditions throughout the plant to prevent *Salmonella* and *Listeria* growth in static materials; (4) controlling condenser cooling water to prevent potential *Salmonella* and other bacterial contamination; (5) controlling sampling and cleanout ports on the evaporator for buildup of static material and avenues for airborne contaminants; and (6) controlling product flow through the plant to prevent unnecessary product movement between areas that may increase the likelihood of cross-contamination.

As stated above, contaminants may enter the product in the air introduced into the spray-drying equipment during the spray- drying process. Air can contain free microorganisms or particulate material that is contaminated with microorganisms. Controls to prevent microbial contamination of the formula by airborne sources must address not only the presence of microorganisms themselves but also the sources of dust, moisture, and other airborne contaminants that may be sources of microbial contamination. Therefore, proposed § 106.50(d)(2) requires that manufacturers filter the intake air before heating to remove dust or other air-borne gross particulates that can result in the production of adulterated formula.

FDA is proposing to require that manufacturers control the removal of air from finished product containers (proposed § 106.50(d)(3)) and ensure that containers of finished products are properly sealed (proposed § 106.50(d)(4)), that visible closure and seal defects are detected (proposed § 106.50(d)(4)(i)), and that destructive tests are performed to determine closure strength (proposed § 106.50(d)(4)(ii)). These requirements are necessary to prevent oxidation and deterioration of nutrients in the formula caused by air or contaminants during the product's shelf life. FDA is also proposing that equipment that is used to prevent adulteration be monitored, either by personnel or monitoring equipment, to alert the manufacturer to malfunctions (see § 106.50(e)). As a result of such monitoring, the manufacturer will be

able to minimize the amount of product produced subject to a malfunction that may develop and to take prompt corrective actions.

In order to prevent rejected in-process materials from being inadvertently commingled with acceptable materials, FDA is proposing that manufacturers establish controls that ensure that the rejected materials are clearly identified and quarantined, and that reprocessed materials will not produce adulterated formula (see § 106.50(f)).

9. Controls to Prevent Adulteration from Microorganisms

An infant formula that is contaminated with microorganisms may, depending on the characteristics of the microorganisms, raise a safety concern that would cause the infant formula to be adulterated under section 402(a)(1) of the act. For example, all serotypes of the genus *Salmonella* can cause illness (often gastrointestinal) in infants and adults (Refs. 33 and 34) and the infectious dose is low (Ref. 35). Moreover, microorganisms that are generally harmless in older children and adults can cause serious bacterial infections in infants because the immune systems of infants are still developing (Ref. 36). For example, newborns and infants are susceptible to infection with *Listeria monocytogenes* that may cause severe illness or death (Ref. 37) and, as in the case of *Salmonella*, the infectious dose is believed to be low (Ref. 38).

Likewise, *Staphylococcus aureus* is harmful to infants because some strains of this microorganism produce an enterotoxin that causes acute gastrointestinal illness (nausea, vomiting, cramps) soon after the food is ingested (Ref. 39). *Bacillus cereus* can produce diarrhea and vomiting in adult humans (Ref. 40) when food contaminated with at least 10^5 *B. cereus* cells is consumed. The infectious dose of *B. cereus* for infants is not known; however, as already noted, infants are more susceptible to bacterial infections than are healthy adults and older children because the immune systems of infants are not fully developed.

FDA has long held that health concerns may arise due to the presence of any detectable *Salmonella*, *Listeria*, or *S. aureus* bacteria in infant formula or due to levels of *B. cereus* that exceed 1,000 ''colony forming units'' (CFU's) per gram (g) of a powdered infant formula. Such health concerns would cause the agency to consider an infant formula that is so contaminated to be adulterated under section 402(a)(1) of the act (see 54 FR 3783, Jan. 26, 1989, and 56 FR 66566, Dec. 24, 1991).

Moreover, the presence of microorganisms in an infant formula reflects that the formula was prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health and therefore is adulterated under sections 402(a)(4) and 412 of the act. For example, the presence of *Escherichia coli* in a sample of infant formula is an indicator of fecal contamination, implying that the infant formula has been contaminated by manufacturing practices conducted under insanitary conditions and therefore is adulterated under sections 402(a)(4) and 412 of the act. In addition, consistent with the standard adopted by the International Commission on Microbiological Specifications for Foods (ICMSF) of the Food and Agricultural Organization of the United Nations and the World Health Organization (WHO) and based on the results from FDA and Canadian Surveys (Refs. 41, 42, and 43), an aerobic plate count (APC) (i.e., the number of microorganisms that will grow under certain specified conditions) that is greater than 10,000 CFU's per g of a powdered infant formula evidences that the formula has been prepared, packed, or held under insanitary conditions.

Illnesses from the use of microbiologically contaminated infant formulas have occurred (Ref. 33). Moreover, as recently as May 1993, infant formula contaminated with *Salmonella* bacteria was the subject of a recall (Ref. 44). Thus, contamination of infant formula with microorganisms of public health significance is more than a theoretical possibility. Therefore, FDA has tentatively concluded that manufacturers need to have in place controls to ensure that formulas are not microbiologically contaminated at levels of public health significance, and that, if they are, those formulas do not enter interstate commerce. Proposed § 106.55 requires manufacturers to establish such controls.

Proposed § 106.55(a) requires that manufacturers of liquid infant formula comply with the procedures specified in part 113. These products are thermally-processed low-acid foods that are packaged in hermetically sealed containers that are heated to achieve commercial sterility. Therefore, they are appropriately subject to the requirements of part 113.

Proposed § 106.55(b) requires that manufacturers of powdered infant formula test representative samples of every batch of the formula at the final product stage, before distribution, to ensure that the infant formula meets the microbiological quality standards specified in proposed § 106.55(c). This proposed requirement is necessary because although powdered infant formulas are heat treated during processing, they are not thermally processed to achieve commercial sterility. Proposed § 106.55(b) requires testing at the final product stage because microbiological contamination can be inadvertently introduced by ingredients at any time during production or through improper processing or holding procedures (Ref. 45).

Proposed § 106.55(c) establishes that any powdered infant formula that contains any microorganism at levels that exceed the microbiological quality standards for that microorganism as listed in this section will be deemed to be adulterated under sections 402 and 412 of the act. Proposed § 106.55(c) defines microbiological quality standards as the maximum allowable number of microorganisms present in 1 g of dry formula, expressed as CFU/g or ''most probable number'' (MPN)/g, and herein designated the ''M value'' for the specific microorganism.

The microorganisms for which FDA is proposing M values are those that are of known public health significance or that are indicators that the formula have been prepared, packed, or held under insanitary conditions. The microorganisms and each proposed M value listed in proposed § 106.55(c) are adapted from guidelines previously published and discussed in the proposed and final rules on infant formula record and record retention requirements (see 54 FR 3783, Jan. 26, 1989, and 56 FR 66566, Dec. 24, 1991, respectively). The agency notes, however, that microorganisms that must be tested for in infant formula and the proposed M values for each microorganism listed in this proposed rule represent minimum requirements for the microbiological quality of an infant formula based on standards and methods currently available.

a. *Aerobic plate count (APC).* Proposed § 106.55(c) establishes an APC M value of 10,000 CFU/g as the maximum level that is consistent with sanitary conditions in the facility in which a powdered infant formula is produced. An APC M value greater than the proposed standard indicates that the formula was produced under insanitary conditions whereby it may have been rendered injurious to health and thus is adulterated under sections 402(a)(4) and 412 of the act.

The APC is the number of microorganisms that will grow on the APC nutrient medium, incubated at 35 °C for 24 hours in air (Ref. 46). ''Microorganisms'' (as defined in

proposed § 106.3(k)) include yeasts, molds, bacteria, and viruses. The APC medium supports the growth of most microorganisms, including yeasts, molds, and all bacteria required to be tested for under proposed § 106.55(c); however, the APC medium does not support the growth of viruses. The APC count is expressed in CFU's because multiple microorganisms may adhere together or attach to the same location on an agar plate, and microbiologists cannot determine whether one or several individual microorganisms initiated the colony that they detect growing on the plate.

This M value for the APC proposed in § 106.55(c) is consistent with the standard adopted by the ICMSF and the WHO and the results from FDA and Canadian Surveys (Refs. 41, 42, and 43). The ICMSF based its standards on the degree of health hazard the microorganisms present and conditions of use of the product (Ref. 41).

FDA has tentatively arrived at this APC M value because the microbial quality of products consumed by infants is of primary concern (Ref. 43). When infant formulas are produced under good commercial processing, the available evidence shows that the APC will be below this M value (Refs. 42 and 43). The agency is notaware of adverse events occurring in infants who consumed products with an APC below this M value.

b. *Coliforms, fecal coliforms, and E. coli. E. colli* are bacteria, including some strains that are pathogenic for infants, that thrive in the human intestinal tract. The presence of *E. coli* in a sample of powdered infant formula is an indicator that the infant formula has been contaminated by manufacturing practices conducted under insanitary conditions and therefore is adulterated under sections 402(a)(4) and 412 of the act.

E. coli bacteria are a subset of a more diverse group of bacteria known collectively as fecal coliforms, which also thrive in the human intestinal tract and therefore are also indicators of fecal contamination. Fecal coliforms are destroyed by pasteurization, and the presence of these microorganisms in a pasteurized product evidences that there has been post-process contamination of the formula (Ref. 47). Fecal coliforms in turn are a subset of a still further diverse group of bacteria known as coliforms, which include bacteria that may or may not be indicators of fecal contamination. However, contamination with coliforms is a reliable indicator of post-process contamination of the formula, even if the source of the contamination is not fecal.

In previously issued guidelines, the agency recommended that powdered infant formulas be tested for the presence of *E. coli* (54 FR 3783); however, one comment on this recommendation suggested that, to allow greater flexibility and reduce the cost for manufacturers, the manufacturer should be given the option of testing for coliforms, fecal coliforms, or *E. coli.* Specific tests for contamination with *E. coli* provide the most definitive evidence of fecal contamination, but tests for specific bacteria are more cumbersome than general tests for a group of bacteria such as fecal coliforms. Similarly, general tests for fecal coliforms are more cumbersome than universal tests for an even more diverse group of bacteria such as coliforms.

The agency is proposing in § 106.55(c) that manufacturers screen their samples of powdered infant formula for evidence of contamination with *E. coli* using sequential tests for detecting and enumerating coliforms and fecal coliforms. Under the proposal, manufacturers ordinarily would only perform the simplest test (i.e., the test for coliforms) using a test sample of the infant formula. The results of the coliform test determine whether the manufacturer needs to followup with a more specific test for fecal coliforms using as the test sample cultured bacteria prepared during the coliform test. As discussed below, the agency is not proposing that manufacturers followup a positive result in the fecal coliform test with a more specific test for *E. coli* but rather is proposing that a violative sample in the fecal coliforms test will represent conclusive evidence that the infant formula is adulterated.

The general test for coliforms is an example of an MPN test. MPN counts are estimates of the number of organisms present in a sample. Methods resulting in an MPN require inoculation of multiple tubes of liquid culture medium with multiple dilutions of the sample. The method specified in FDA's Bacteriological Analytical Manual (BAM) (Ref. 46) requires inoculation of 3 replicate tubes of culture medium with each of 3 sample dilutions, for a total of 9 tubes. The tubes contain culture medium selective for the microorganism of interest. After appropriate incubation (time, temperature, and atmosphere), each tube is scored as positive or negative for the presence of the organism. Examples of a positive result include the presence of growth, a biochemical color change, and the production of gas.

A mathematical formula is used to calculate the MPN of microorganisms present based on the number of positive tubes in each of the three separate dilutions. Since the calculation in question involves a repetitious process, the mathematical formula used to calculate the MPN has been employed to create easy-to-use tables that are available in the BAM and in other books of statistical tables. Most tables present both a value for the MPN and confidence limits for that value. The calculated table values for the MPN, using BAM methods, are dependent on the level of the dilution in which a positive result is found. The following table values are based on an inoculation series of 0.1, 0.01 g, and 0.001 g (or mL) of the infant formula. When no tubes in any dilution produce a positive result, the calculated MPN value is zero.[3] When a single tube in the greatest dilution (least concentrated) produces a positive result, the calculated MPN value is equal to 3.01.[4] When a single tube in the middle dilution produces a positive result, the calculated MPN value is equal to 3.05.[5] In all other situations in which there is a positive result in at least one tube (including a single positive tube in the lowest dilution (greatest concentration)), the calculated MPN value is greater than 3.05.

If no tubes in any dilution produce a positive result in a test for bacterial contamination of a powdered infant formula (i.e., if the MPN is zero), such contamination is unlikely. If a single tube in any dilution produces a positive result in a test for bacterial contamination of the product, such contamination is a possibility. However, there are two situations in which a single positive tube is generally considered to reflect a false positive test result: (1) When no tube in the lowest dilution (greatest concentration) produces a positive result, but a single tube in the middle dilution produces a

[3] The calculated MPN value of zero when no tubes in any dilution produce a positive result is a recent change that appears in the MPN tables of the 8th ed. of the BAM. In previous editions of the BAM, the calculated MPN value when no tubes in any dilution produce a positive result was ''less than 3.''

[4] The calculated MPN value of 3.01 when a single tube in the greatest dilution produces a positive result is a recent change that appears in the MPN tables of the 8th ed. of the BAM. In previous editions of the BAM, the calculated MPN value when a single tube in the greatest dilution produces a positive result was 3.

[5] The calculated MPN value of 3.05 when a single tube in the middle dilution produces a positive result is a recent change that appears in the MPN tables of the 8th ed. of the BAM. In previous editions of the BAM, the calculated MPN value when a single tube in the middle dilution produces a positive result was 3.

positive result (i.e., the calculated MPN value is equal to 3.01); or (2) when no tube in the lowest dilution produces a positive result, but a single tube in the greatest dilution (least concentration) produces a positive result (i.e., the calculated MPN value is equal to 3.05). FDA considers that if a sample of a powdered infant formula produces positive test results that reflect one of these two situations, bacterial contamination also is unlikely.

However, in all other situations (e.g., if a single tube in the lowest dilution (greatest concentration) produces a positive result, or if two or more tubes in any dilution produce a positive result), bacterial contamination of a powdered infant formula is likely. Therefore, when the calculated MPN value in a test for bacterial contamination is greater than 3.05, that is if a sample of powdered infant formula produces positive test results in which a single tube in the lowest dilution produces a positive result or in which two or more tubes in any dilution produce a positive result, the powdered infant formula likely is contaminated with bacteria.

FDA is proposing to use the calculated MPN values in the BAM as a means of setting a numerical specification because these tables are generally available, represent standard practice in the industry, and provide a simple way to classify samples as violative or nonviolative. Based on the above discussion of calculated MPN values, FDA is proposing in § 106.55(c) that powdered infant formula be classified as nonviolative for coliforms in all situations in which the calculated MPN value is less than or equal to 3.05 and classified as presumptively violative for coliforms in all situations in which the calculated MPN value is greater than 3.05. In other words, FDA is proposing that an MPN value of 3.05 represents the maximum allowable number of coliforms present in 1 g of dry infant formula. This proposal is consistent with current FDA infant formula microbiological guidelines. The agency requests comment on the specification of 3.05 MPN/g as the maximum allowable number of coliforms in dry infant formula.

FDA has stated that infant formula with a calculated MPN value of greater than 3.05 in the coliform test is presumptively violative because, under proposed § 106.55(c), the manufacturer may either consider the sample violative without further testing or may conduct an additional test, the fecal coliform test. Although an MPN value of greater than 3.05 MPN/g is a valid quality indicator of microbial contamination, coliform contamination may not be fecal in origin, and it may not reflect the presence of infant pathogenic microorganisms. Therefore, FDA has tentatively concluded that an infant formula for which an MPN value of greater than 3.05 MPN/g is found in the coliform test need not be considered violative if a negative result is found in a more specific test for fecal coliforms.

If the coliform test using powdered infant formula samples results in an M value greater than 3.05 MPN/g, the manufacturer may use the cultured bacteria from one or more of the tubes producing the positive result as a sample inoculum for the fecal coliform test. A sample inoculum producing an MPN value in the fecal coliform test of less than or equal to 3.05 would indicate that the coliform contamination is not fecal in origin, because under incubation conditions that are specific for fecal coliforms, the bacteria were not detected. The testing would effectively screen out coliforms that are not of concern, which is not possible with the more general test. Therefore, FDA has tentatively concluded that an MPN value less than or equal to 3.05 in the fecal coliform test be classified as nonviolative. FDA also has tentatively concluded that an MPN value greater than 3.05 in the fecal coliform test is a valid quality indicator demonstrating that the formula contains fecal coliforms such as *E. coli* and, therefore, is adulterated under sections 402(a)(4) and 412 of the act. The agency is proposing that powdered infant formula that results in an MPN value greater than 3.05 in the fecal coliform test be classified as violative.

If the *E. coli* test was performed, the sample inoculum would be the cultured bacteria from positive tubes in the fecal coliforms test. However, the agency is not proposing to require specific testing for the presence of *E. coli,* or to set a specification for an M value for *E. coli,* because the specification of less than or equal to 3.05 MPN/g in the fecal coliforms test is sufficient to ensure that nonviolative samples do not contain *E. coli* since *E. coli* is a type of fecal coliform. Moreover, FDA has tentatively concluded that an MPN value greater than 3.05 in the fecal coliform test is a sufficient quality indicator of fecal contamination that the agency need not propose, as an option, that a manufacturer may conduct an additional specific test for the presence of *E. coli.* The agency requests comments on the proposed requirements for sequential testing for coliforms and fecal coliforms, with no testing for *E. coli.*

c. *Salmonella.* Tests for the presence of *Salmonella* involve the enrichment in a broth of the entire analytical unit followed by plating onto culture plates rather than the culture of a series of dilutions that is performed in tests for coliforms. A positive result in a test for *Salmonella* is based on the detectable presence of the microorganism on the culture plate rather than on the mathematical calculations that result in a MPN.

Proposed § 106.55(c) requires that powdered infant formula be tested for *Salmonella* and provides that the formula is adulterated if any *Salmonella* is found. All serotypes of this genus of bacteria can cause illness (often gastrointestinal) in infants and adults (Refs. 33 and 34). The presence of any *Salmonella* in infant formula could render it injurious to an infant who consumes it because the infectious dose of these bacteria is low (Ref. 35). Therefore, FDA has tentatively concluded that the risk from *Salmonella* is of such significance that an M value of zero (i.e., none detectable) for *Salmonella* in infant formula is necessary to protect the health of infants.

d. *Listeria monocytogenes.* Tests for the presence of *L. monocytogenes* are similar to those for *Salmonella* and a positive result is based on the detectable presence of the microorganism on the culture plate rather than on the mathematical calculations that result in a MPN.

Proposed § 106.55(c) requires that powdered infant formula be tested for *L. monocytogenes* and provides that the formula is adulterated if any *L. monocytogenes* is found. Individuals with immune systems that make them susceptible to infections, such as newborns and infants with incompletely developed immune systems, are susceptible to infection with *L. monocytogenes* which may cause severe illness or death (Ref. 37). The infectious dose of this bacterium is believed to be low (Ref. 38). Because the specific dose of this bacterium that may cause illness is not known but is believed to be low, FDA has tentatively concluded that the risk from *L. moncytogenes* is of such significance that an M value of zero (i.e., none detectable) for *L. monocytogenes* in powdered infant formula is necessary to protect the health of infants. The agency requests comment on this proposed specification for *L. monocytogenes.*

e. *Staphylococcus aureus. S. aureus* is harmful to infants because some strains of this microorganism produce an enterotoxin that causes acute gastrointestinal illness (nausea,

vomiting, cramps) soon after the food is ingested (Ref. 39). Tests for *S. aureus* involve liquid culture of series of dilutions as was discussed previously in reference to coliform and fecal coliform testing and results are calculated as MPN based on tables in the BAM. Proposed § 106.55(c) requires that powdered infant formula be tested for *S. aureus* and establishes an M value of 3.05 for this microorganism. FDA has tentatively concluded that the risk from *S. aureus* is of such significance that an M value of 3.05 is necessary to protect the health of infants.

f. *Bacillus cereus.* Tests for *B. cereus* involve liquid culture of a series of dilutions as was discussed previously in reference to coliform and fecal coliform testing and results are calculated as MPN based on tables in the BAM. Proposed § 106.55(c) requires that powdered infant formula be tested for *B. cereus* when the APC exceeds 100 CFU/g and establishes an M value for *B. cereus* of 100 MPN/g or 100 CFU/g. This proposed M value for *B. cereus* is lower than the M value of 1,000 MPN/g or 1,000 CFU/g in the current recommended infant formula microbiological guidelines (54 FR 3783). *B. cereus* can produce diarrhea and vomiting in adult humans (Ref. 40) when food contaminated with at least 10^5 *B. cereus* cells is consumed. The infectious dose of *B. cereus* for infants is not known; however, because the immune systems of infants are not fully developed, infants are more susceptible to bacterial infections than are healthy adults and older children. In the absence of data on the dose of *B. cereus* capable of causing disease in infants, the agency is concerned that a safety standard of 1,000 MPN/g or 1,000 CFU/g poses a potential risk to infants who consume rehydrated formula because *B. cereus* in rehydrated powdered infant formula is capable of rapid growth and can reach 4.9×10^6 cells/g within 24 hours at 26 °C (Ref. 48), a level sufficient to cause disease. Therefore, FDA has tentatively concluded that the risk from *B. cereus* is of such significance that an M valve that is lower than the current standard of 1,000 MPN/g or 1,000 CFU/g is necessary to protect the health of infants.

Powdered infant formulas and similar products (e.g., powdered milk) produced under CGMP contain less than 100 MPN/g or 100 CFU/g of *B. cereus* (Refs. 43 and 48). Additionally, an FDA survey of different production lots of milk-, soy-, and protein hydrolysate-based powdered infant formulas (Ref. 49) showed that the maximum APC was 103 CFU/g, and that the proportion of *B. cereus* in the samples ranged from 1.2 to 63.9 percent of the APC. Therefore, FDA has tentatively concluded that an M value of 100 MPN/g or 100 CFU/g for *B. cereus* will adequately protect the health of infants. Moreover, because this M value is higher than the *B. cereus* levels typically found in infant formula currently being produced (Refs. 43, 48, and 49), the proposed M value of 100 MPN/g or 100 CFU/g will not be overly burdensome.

g. *Methods.* Proposed § 106.55(c) states that the agency intends to determine compliance with the proposed M values using the methods in the BAM. These methods provide reproducible, consistent, and accurate results at different laboratories. The agency proposes to incorporate the BAM by reference in § 106.55(c) in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. While manufacturers may use other equivalent methods, a manufacturer who uses methods that do not provide results that are consistent with the results obtained by methods approved by FDA will bear the risk that the firm's product is not in compliance with the law.

The agency intends to test for *Salmonella* using the method described in Chapter 5, BAM, including the sample preparation procedures described in section C, paragraph 1 and the sampling plan described in Chapter 1, BAM; for *L. monocytogenes* using the method described in Chapter 10, BAM and the sampling plan described in Chapter 1, BAM; for coliforms, fecal coliforms, and *E. coli* using the MPN method described in Chapter 4, BAM; for *S. aureus* using the MPN method described in Chapter 12, BAM; for *B. cereus* using the MPN or plate count method described in Chapter 14, BAM. The agency intends to determine the APC using the method described in Chapter 3, BAM. All chapter references are to the 8th ed. BAM. FDA intends to update the reference to reflect the most recent edition of the BAM at the time the final rule based on this proposed rule is issued.

h. *Records.* Proposed § 106.55(d) requires that manufacturers make and retain records, in accordance with proposed § 106.100 (e)(5)(ii) and (f)(7) on the testing of infant formula for microorganisms. As discussed in the description of the revisions to proposed subpart F of part 106, FDA has the authority to require such records under section 412(b)(4)(A)(i) of the act. These records will document whether the batch of powdered infant formula meets the microbiological quality standards of proposed § 106.55(c) and is therefore not adulterated. Records that describe the full methodology for testing powdered infant formula for microbiological quality will provide consistency in the testing of the microbiological quality of the formula, even if different laboratory personnel conduct the tests. The accuracy and reproducibility of microbiological quality testing depend on the procedure used to conduct the test. In addition, the records will provide the manufacturer with data to evaluate any complaints received associated with a particular batch of infant formula by showing whether microbiological contamination could have contributed to the adverse event.

10. Controls to Prevent Adulteration During Packaging and Labeling of Infant Formula

Because consumers rely on correct labels to select a formula to meet their childrens' individual needs and to have proper instructions for the use of the formula, FDA is proposing § 106.60(a) which requires manufacturers examine packaged and labeled infant formula to ensure that containers and packages bear the correct labels, use-by dates, and traceability codes. The proposal also requires that labels be designed, printed, and applied so that they remain attached and legible during processing, handling, storage, and use (proposed § 106.60(b)), and that all formula held in a single package be the same product bearing the same traceability code, and that the package carry the product name, name of the manufacturer, and the code (proposed § 106.60(c)).

These proposed requirements will ensure that infants who have allergies will not be placed at risk by consuming formula containing ingredients to which they are allergic, and that consumers will be aware of the date when the product may no longer be appropriate for use. In addition, the traceability codes will show the origin of the product if there were a recall, and the packaging requirements will make it more difficult for counterfeit formula, or formula with counterfeit labels, to be shipped in interstate commerce. There have been cases of counterfeit shipments in which a single package held more than one product, or held a single product which bore more than one code. The proposed regulations are not only intended to reduce the incidence of counterfeit activities, but to ensure that firms that receive the formula are aware that only one product should be in the packaging, and that all containers should be identified with the code shown on the package. This requirement will not impose an additional burden on industry because manufacturers routinely package a

single infant formula product bearing the same code.

11. Controls on the Release of Finished Infant Formula

Proposed § 106.70(a) requires that the manufacturer determine that each batch of formula meets all of the manufacturer's specifications before releasing the batch for distribution. Specifically, each batch must meet the requirements of § 106.55 on microbiological contamination to ensure that the infant formula does not contain microorganisms at levels that may be injurious to the health of infants and render the formula adulterated and must meet the requirements of § 106.91(a) on quality control procedures to ensure that the infant formula provides the required nutrients at the required levels, and that it provides any nutrient added by the manufacturer. Proposed § 106.70(a) is designed to ensure that any infant formula that fails to meet the manufacturer's specifications, or that is adulterated for any reason, will not be introduced into interstate commerce.

Proposed § 106.70(b) requires that each batch of infant formula that fails to meet the manufacturer's specifications be rejected. Although proposed § 106.70(b) recognizes that the formula may be reprocessed, it requires that the reprocessed product be shown to meet the requirements of § 106.70(a) before the product is released. FDA has tentatively concluded that this proposed requirement is necessary to ensure that any defect that caused a batch of infant formula to be rejected is corrected before the formula is released into commerce.

Proposed § 106.70(c) requires that an individual qualified by training or experience conduct an investigation of a finding that a batch of infant formula fails to meet any manufacturer's specifications. This investigation is necessary to determine why such a failure occurred and to assist the manufacturer in developing controls to ensure that such a failure does not reoccur. FDA has proposed to require that the individual who conducts the investigation be qualified to ensure that the investigation is properly conducted.

12. Traceability

Section 412(g)(1) of the act requires that each manufacturer make and retain such distribution records as may be necessary to effect and monitor recalls of the formula, and section 412(b)(4)(A)(vi) requires that each manufacturer retain all complaints concerning infant formulas that may reveal the possible existence of a hazard to health. Therefore, infant formulas must be traceable to permit identification of the product that is the subject of a complaint and to make it possible to determine whether that batch of infant formula presents a possible hazard to health. Traceability of an infant formula is also necessary so that the recall requirements of the act can be met.

The agency's view, based on its experience, is that coding is the most effective method for ensuring traceability. It provides a uniform system that is able to identify large numbers of batches of infant formula with a distinctive code that is easily understood and that can be used by manufacturers, retailers, and consumers. A code also allows a large amount of information to be presented on the container of infant formula in a very small space. Therefore, the agency is proposing, under sections 412 (b)(4)(A)(vi) and (g)(1) and 701(a) of the act that batches of infant formula be identified with a distinctive code that will allow the traceability of an infant formula.

Current § 106.90 requires that manufacturers ensure traceability by coding all infant formulas in conformity with the coding requirements in § 113.60(c) for thermally processed low-acid foods packaged in hermetically sealed containers. Section 113.60(c) requires that the code identify the establishment where the product is packed, the product contained therein, the year packed, the day packed, and the period during which packed, and that the packing period code be changed with sufficient frequency to permit ready identification of lots during their sale and distribution. FDA is proposing to carry the requirement that manufacturers code their product in accordance with § 113.60(c) forward in proposed § 106.80(a).

FDA has tentatively determined that it is appropriate to code liquid infant formulas in this manner because they are thermally processed low-acid foods, and a batch is produced in a relatively short period of time, usually a day. It also may be appropriate for coding some powdered infant formulas in this manner if they are processed in a short enough time to make the day packed and the period during which packed meaningful information.

Proposed § 106.80(b) allows for alternative coding of batches of powdered infant formula. Powdered infant formula is usually manufactured in stages over a longer period of time than liquid infant formula. Some powdered infant formulas are dry mixed in a number of stages over an extended period of time. In other cases, powdered infant formula is mixed in liquid form at one manufacturing facility and shipped to a second site for spray drying and packaging. Powdered infant formula manufacturing is often not completed in a short enough period of time for coding based on the date packed or the period of time in which it was packed to be meaningful information. Therefore, under the alternate method that FDA is proposing, a sequential code would be assigned so that all the essential information needed to track any problems with the infant formula could be determined.

13. Audits of CGMP

Proposed § 106.90 requires that manufacturers (or their agents) conduct regularly scheduled audits to determine whether they are complying with CGMP. This provision derives from section 412(b)(2)(B)(iv) of the act, which requires that the CGMP include ''the conduct by the manufacturer of an infant formula or an agent of such manufacturer of regularly scheduled audits to determine that such manufacturer has complied with the regulations prescribed under'' section 412(b)(2)(A) of the act. Section 412(b)(2)(A) requires that the Secretary (and by delegation FDA) establish CGMP's by regulation.

FDA is proposing to require that regularly scheduled audits be part of CGMP because such audits are the best way to ensure overall compliance with CGMP and to identify recurring problems that may dictate an alteration in the master manufacturing order. For example, regularly scheduled audits of all deviations from the manufacturer's specifications or procedures will accentuate deviations that occur repeatedly and will enable the manufacturer to identify specifications or procedures that should be reassessed.

Section 412(b)(2)(B)(iv) of the act also specifies that such audits are to ''be conducted by appropriately trained individuals who do not have any direct responsibility for the manufacture or production of infant formula.'' FDA is therefore proposing that an individual be knowledgeable in all aspects of infant formula production perform the audit. Without such broad knowledge, the individual conducting the audit will not be able to adequately evaluate the manufacturer's production and in-process control procedures. In addition, because the purpose of the audit is to determine whether the manufacturer is complying with the CGMP regulations issued under section 412(b)(2)(A) of the act, the agency has tentatively concluded that the person conducting the audit needs to be knowledgeable in

these regulations. Without such knowledge, the person would be unable to make the determinations that are the very purpose of the audit.

The requirement that the audit be performed by an individual who has no direct responsibility for the matters being audited is one way to ensure the objectiveness of the audit process. The person should be free of any past involvement in the activities being audited because the audit is intended to uncover any problems or shortcomings in the manufacturer's procedures. A person who has been involved may feel that finding problems will reflect poorly on his or her work. Therefore, FDA has tentatively concluded that the audit must be conducted by someone who has no direct interest in the outcome of the audit.

C. Quality Control Procedures

1. Introduction

FDA is proposing to redesignate and revise subpart B of part 106 as subpart C of part 106. Under this proposal, several sections of the current regulations will be revoked, and several sections will be redesignated without change. The latter sections are being recodified, however, to fit the organization of the proposed regulations. Table II describes the current and proposed regulations as follows:

TABLE II

Current regulation	Proposed regulation
INGREDIENT CONTROL	
§ 106.20(a), § 106.20(b)(1), § 106.20(b)(2).	Changed by §§ 106.91(a)(1) and 106.40(d).
IN-PROCESS CONTROL	
§ 106.25(a)	§ 106.50(a)(1).
§ 106.25(b)(1)	Omitted.
§ 106.25(b)(2)	§ 106.91(a)(4).
§ 106.25(b)(3)	§ 106.91(a)(2).
§ 106.25(b)(4)	§ 106.91(a)(4) with modification.
§ 106.25(b)(5)	§ 106.91(a)(3) with modification.
FINISHED PRODUCT EVALUATION	
§ 106.30(a)	§ 106.91(a).
§ 106.30(b)(1)(i)	§ 106.91(a)(3).
§ 106.30(b)(1)(ii)	§ 106.91(a) with modification.
§ 106.30(b)(2), § 106.30(b)(3).	§ 106.91(b) with modification.
§ 106.30(c)(1)	Omitted.
§ 106.30(c)(2)	§ 106.3(i) §§ 106.91(b)(1) and 106.97(b)(1) with elimination of the osmolality and vitamin D assay.
§ 106.30(d)	Omitted.

FDA is proposing quality control procedures under the authority granted by section 412(b)(2), (b)(3), and (b)(4) of the act, which direct the Secretary (and by delegation, FDA) to establish by regulation the quality control procedures that he or she determines are necessary to ensure that an infant formula provides the required nutrients at the required levels. In the Congressional Record of September 27, 1986, Senator Metzenbaum stated: ''The most important provision of this amendment is the simple requirement that each batch of formula must be tested for each essential nutrient that must be contained in the formula'' (Ref. 1). The quality control procedures in proposed subpart C of part 106 are the minimum practices that manufacturers must implement to ensure that the infant formula that they produce contains the required nutrients at the required levels throughout the shelf life of the product. Under section 412(a)(3) of the act, an infant formula is deemed to be adulterated if the processing of the formula does not comply with quality control procedures prescribed by the Secretary.

2. Nutrient Testing

Proposed § 106.91(a) describes the testing that FDA has tentatively concluded each manufacturer must conduct on each batch of infant formula to ensure that it provides the required nutrients at the required levels and provides any nutrient added by the manufacturer. FDA is proposing these requirements under the authority of two sections of the act. Section 412(b)(2)(B)(i) of the act provides that the quality control procedures shall include requirements for testing, in accordance with section 412(b)(3), of each batch of infant formula for each required nutrient, before distribution of such batch. Section 412(b)(3)(D) of the act states that if the Secretary adds a required nutrient, the Secretary must require that the manufacturer of the infant formula test each batch of such formula for that nutrient in accordance with section 412(b)(3)(A), (b)(3)(B), and (b)(3)(C) of the act.

Current § 106.20(a) and (b)(2), which FDA is proposing to replace with § 106.91(a)(1), do not require that manufacturers analyze nutrient premixes if the premixes come with a supplier's guarantee or certification. Proposed § 106.91(a)(1), however, requires that each nutrient premix used in the manufacture of an infant formula be tested by the formula manufacturer for each nutrient that the manufacturer is relying on the premix to provide to ensure that the premix complies with the manufacturer's specification. This change is required by section 412(b)(3)(B) of the act. Section 412(b)(3)(B) was included in the 1986 amendments because infant formula manufacturers were increasingly relying on the use of formula premixes, and Congress felt that relying on a premix supplier's written assurance that its premix product was properly tested was inadequate (Ref. 1). In 1985, the Department of Justice sought an injunction against a premix supplier because, ''as a result of inadequate quality control, numerous * * * vitamin and mineral mixes—used in infant formula—have been misbranded and adulterated'' (Ref. 3). The premix supplier entered into a consent decree of permanent injunction that enjoined it from shipping any of its vitamin/mineral premixes for use in infant formulas until it completed a number of specific acts that were designed to improve its quality control (Ref. 50).

FDA is proposing to redesignate current § 106.25(b)(3) as § 106.91(a)(2), which requires that after the addition of the premix, or at the final-product stage but before distribution, each batch of infant formula be tested to confirm that the nutrients contained in any nutrient premix used in such infant formula are present in each batch of infant formula in the proper concentration. This requirement implements section 412(b)(3)(C)(ii) of the act, which requires that infant formula be tested to ensure that any nutrient premixes used by the manufacturer are actually included in the batch of infant formula in the proper amount. Without this check, inadvertent failure to include the premix could go undetected, and infant formula that is deficient in the nutrients that were to be provided by the premix would be introduced into the market.

Current § 106.30(b)(1)(i) requires that the manufacturer analyze representative samples of each batch of finished infant formula for specific nutrients to assess process degradation. FDA is carrying forward a modified version of this requirement in proposed § 106.91(a)(3), which requires that each batch of infant formula be tested for vitamins A, C, and

E and thiamin at the final-product stage, before distribution. This regulation is proposed under section 412(b)(3)(A) of the act, which states: ''At the final product stage, each batch of infant formula shall be tested for vitamin A, vitamin B1, vitamin C, and vitamin E * * *.'' In the Congressional Record, Senator Metzenbaum stated that testing for these vitamins is required at the final-product stage because they are vulnerable to degradation (Ref. 1). Testing at the final-product stage will ensure that these nutrients are present in the infant formula at the end of all the processing steps that may destroy them.

Proposed § 106.91(a)(4) requires that, before distribution, each batch of infant formula be tested for all nutrients required to be included, and any others that have been included, but for which testing to comply with § 106.91(a)(1) or (a)(3) was not conducted. This proposed provision takes a markedly different tack than current § 106.30(b)(1)(ii), which states that no analyses are needed for linoleic acid, vitamin D, vitamin K, choline, inositol, and biotin before release of a batch of infant formula for commercial or charitable distribution. This change in approach is necessary because section 412(b)(3)(C) of the act, which was added by the 1986 amendments, states that each batch of formula must be tested for each nutrient required by the law to be present in an infant formula. Also, manufacturers are adding nutrients not required by § 107.100, such as selenium, to infant formulas. These nutrients meet the definition for ''nutrient'' in proposed § 106.3(m) because they have been identified as essential for infants by NAS through its development of a Recommended Dietary Allowance or an Estimated Safe and Adequate Daily Dietary Intake range. The agency has not objected to the addition of nutrients not required by § 107.100 to infant formulas. However, it is important that the level of these added nutrients be controlled, and that the level of the added nutrient be consistent from batch to batch and be uniform throughout the batch of infant formula.

The level of a nutrient needs to be controlled because some nutrients can be toxic to an infant if given at too high a level. Controlling the level of the added nutrient for consistency from batch to batch and in a particular batch of infant formula will ensure that the infant receives the essential nutrient on a consistent basis and will also ensure that the infant does not receive too high, or too low, a level of the nutrient because the nutrient was not uniform throughout the batch of infant formula.

3. Stability Testing

Current § 106.30(c) requires that the manufacturer, using representative samples collected from finished product batches, conduct stability analysis for selected nutrients with sufficient frequency to substantiate the maintenance of nutrient content throughout the shelf life of the product. The 1986 amendments added subsection 412(b)(2)(B)(ii) to the act, which requires ''regularly scheduled testing, by the manufacturer of an infant formula or an agent of such manufacturer, of samples of infant formula during the shelf life of such formula to ensure that such formulas are in compliance with'' section 412 of the act. To implement this section of the act, the agency is redesignating and revising current § 106.30(b)(3) as proposed § 106.91(b), which requires quarterly collection of samples of infant formula for stability testing to provide a check on nutrient stability. This periodic check will alert the manufacturer if nutrient stability has changed in some unpredicted way so that the formula no longer complies with section 412 of the act. Quarterly testing of infant formulas for nutrient stability is currently conducted by the industry (Refs. 51 and 52), and the agency is not aware of any problems that have resulted from this frequency of testing. The agency requests comment on whether this proposed frequency of sample collection for stability testing is appropriate.

The agency has tentatively concluded that this periodic sample collection to check on nutrient stability must be performed on a batch of each physical form (powder, ready-to-feed, or concentrate) of each infant formula, at each different manufacturing facility, because different forms of the product may contain different ingredients, and different forms of infant formula are subjected to different processing procedures. Therefore, ensuring the nutrient stability of one form of the product, such as the powder, will not answer questions about the nutrient stability of other forms of the product. Thus, the agency has tentatively concluded that each form of the infant formula must be sampled on a periodic basis for nutrient stability. Also, the agency has tentatively concluded that the sampling of one batch of each physical form of each infant formula must be conducted at each manufacturing facility. This proposed requirement is necessary because manufacturers may produce the same infant formula at more than one facility, and the manufacturing conditions at one facility may not be the same as the conditions at another facility. The differences in conditions cannot be allowed to affect the quality of the formula.

Proposed § 106.91(b) further requires testing at the beginning, midpoint, and end of the shelf life of the infant formula. Testing at the beginning of the shelf life shows that the formula is in compliance with the nutrient requirements of the act when it is released for distribution. Testing at the midpoint of the shelf life will alert the manufacturer if any nutrient is deteriorating at a rate different from that predicted, so that the nutrient may not be in the formula at a level to comply with the act throughout the formula's shelf life. Testing at the end of shelf life will ensure that the formula contained all the nutrients needed to comply with the act throughout its shelf life and will provide continued justification for the predicted shelf life.

Additional testing may be necessary to ensure that a formula complies with section 412 of the act throughout its shelf life. Such testing is likely to focus on a particular nutrient and its stability within the matrix of the formulation. This additional testing will ensure that, if there is a significant deterioration in the level of the nutrient in the formula, the manufacturer will be aware of this fact and will be able to take steps promptly to have the product removed from the market, before a significant number of infants are exposed to a deficient product.

The agency is not proposing to specify what frequency is required because manufacturers have experience with the nutrient stability of the infant formula matrices that they produce and are thus in a position to determine how frequently testing is necessary. For example, the manufacturer is in a position to know whether the nutrient levels of a milk-based infant formula need to be tested on a different basis than that of a soy-based product, or whether the nutrient levels of an infant formula that contains hydrolyzed protein needs to be tested more frequently than that of an infant formula that contains non-hydrolyzed protein. Manufacturers will be able to comply with section 412(b)(2)(B)(ii) of the act by testing different nutrients at different frequencies. For example, unstable nutrients, such as vitamins, may require testing on a more frequent basis than more stable nutrients, such as minerals. Proposed § 106.91(b) allows the manufacturers the discretion to determine the necessary frequency of testing to ensure that their infant formula complies with the nutrient

requirements of the act, as long as the minimum testing (i.e., at the beginning, middle, and end of the shelf life) required by proposed § 106.91(b) is accomplished.

Proposed § 106.91(b)(1) provides for an addition to the stability testing required under § 106.91(b). FDA is proposing that the first batch of each form of a new infant formula be subjected to such testing to ensure that the product complies with the nutrient requirements of section 412 of the act throughout its shelf life.

Proposed § 106.91(b)(2) requires the sampling of the first batch of an infant formula in which there has been a change in formulation or in processing that could affect whether the formula is adulterated under section 412(a) of the act and requires testing of these samples for each nutrient that has been, or may have been, affected by the change. The change in formulation or processing referred to here would not be a ''major change'' because a ''major change'' would mean that the formula is a ''new infant formula.'' Examples of the types of changes that are subject to proposed § 106.91(b)(2) are: (1) Reducing a ''required nutrient'' in a minor way or increasing a ''required nutrient'' that is subject to maximum limits in § 107.100 in a minor way; (2) replacing one nutrient form with another form, such as replacing vitamin A acetate with vitamin A palmitate or replacing calcium carbonate with tricalcium phosphate; (3) changing a time-temperature condition of preheating, handling, mixing, or sterilizing an in-process product; or (4) changing the oxygen content of a packaged product that might have a minimal effect on the level of nutrients. Requiring sample collection for stability testing when a manufacturer makes changes such as these in the manufacture of the product will ensure that the manufacturer can verify the predicted shelf life of the changed formula.

Proposed § 106.91(b)(2) requires that the manufacturer ensure that the infant formula meets all the nutrient requirements of section 412 of the act. This provision is proposed under the authority of section 412(b)(2)(A) of the act, which provides for the establishment of CGMP's for infant formulas, including quality control procedures that are necessary to assure that the infant formula provides nutrients in accordance with section 412 (b) and (i) of the act, as well as section 412(b)(2)(B)(ii). If the formulation or processing of the infant formula has been changed, the manufacturer must consider what nutrients may have been affected by the change and test for each of these nutrients in the final-product stage of the first batch of the changed formula. For example, if the manufacturer makes a change in the amount of a protein source used in the infant formula, the firm must test the formula for protein content and for any nutrients provided endogenously to the formula by the protein, such as minerals like calcium and phosphorus. The manufacturer is aware of how much of each mineral it is relying on the protein source to provide to the formula. When the amount of the protein source used in the formula is changed, the manufacturer must test for the level of all nutrients it relies on the protein source to provide to the formula to ensure that all nutrients in the formula meet the requirement of § 107.100.

4. Quality Control Records

Proposed § 106.91(c) requires that manufacturers make and retain records of the results of all testing performed on the batch of infant formula in accordance with proposed § 106.100(e)(5)(i) and a full description of the methodology used in accordance with proposed § 106.100(f)(7). As discussed in the description of the proposed revisions to subpart F of part 106, FDA has authority to require these records under section 412(b)(4)(A)(i) of the act. Providing a record of the results of quality control testing will verify that each nutrient required by § 107.100 is present in each batch of infant formula at the required level, and that any nutrients added by the manufacturer are present at the appropriate level. These records will show the levels of nutrients in the formula and will provide data needed to evaluate a batch of infant formula if problems, such as adverse events in infants, occur later with that particular batch. Records that describe the full methodology used to conduct the quality control testing will provide consistency in the procedure that the manufacturer is using to test for the nutrients in each batch of infant formula, even when different laboratory personnel are conducting the testing. The accuracy and reproducibility of quality control testing depend on the procedure used to conduct the test.

5. Audits of Quality Control Procedures

Proposed § 106.92 requires that the manufacturer of an infant formula, or an agent of such a manufacturer, conduct regularly scheduled quality control audits to ensure that an infant formula provides required nutrients and has been manufactured in a manner designed to prevent adulteration. Proposed § 106.92 derives from section 412(b)(2)(B)(iv) of the act, which requires that the quality control procedures prescribed by the Secretary include ''the conduct by the manufacturer of an infant formula or an agent of such manufacturer of regularly scheduled audits to determine that such manufacturer has complied with the regulations prescribed under'' section 412(b)(2)(A) of the act (stating that the Secretary (and FDA by delegation) establish by regulation ''quality control procedures that the Secretary determines are necessary to assure that an infant formula provides nutrients in accordance with'' section 412 (b) and (i) and ''is manufactured in a manner designed to prevent adulteration of the formula''. FDA is proposing to require that regularly scheduled audits be part of quality control procedures because such audits will document compliance with the quality control procedures and will identify recurring problems that may dictate an alteration in the master manufacturing order. For example, regularly scheduled audits of the results of tests of nutrient levels in infant formulas and of any deviations from the manufacturer's specifications or procedures for acceptable nutrient levels will reveal deviations that occur on a repeated basis and will enable the manufacturer to identify specifications or procedures that should be reassessed.

Proposed § 106.92 further requires that the audits be performed by an individual who, as a result of education, training, and experience, is knowledgeable in all aspects of infant formula production and of the agency's regulations concerning quality control procedures, but who has no direct responsibilities for the matters being audited. The legal authority for this provision, the importance of the responsible individual's knowledge in all aspects of infant formula production and the agency's regulations, and the need for the audit to be performed by an individual who has no direct responsibility for the matters being audited were discussed previously under the proposed CGMP regulations in § 106.90.

By proposing different regulations (proposed §§ 106.90 and 106.92) that require audits of CGMP and of quality control procedures, the agency is not suggesting that it will require that separate audits be conducted. These regulations are being proposed separately to make clear that the regularly scheduled audits required by section 412(b)(2)(B)(iv) of the act are an aspect both of CGMP and of quality control procedures. The agency would have no objection to a combined audit

of CGMP and of quality control procedures.

6. Revocation of the Requirement for Determination of Vitamin D by the Rat Bioassay Method

FDA is proposing to revoke the requirement in current § 106.30(c)(2) for the determination of vitamin D by a rat bioassay method. This rat bioassay for vitamin D is no longer a viable assay because appropriate animals for conducting this test are difficult to acquire (Ref. 53), and an alternate analytical method for the determination of vitamin D in infant formulas has been approved by the Association of Official Analytical Chemists (Ref. 54).

D. Conduct of Audits

Section 412(b)(2)(B)(iv) of the act provides that CGMP and quality control procedures include regularly scheduled audits to determine whether the manufacturer is complying with CGMP, including following the quality control procedures that are necessary to ensure that an infant formula provides the required nutrients at the required levels, and whether it is operating in a manner designed to prevent adulteration of the formula. FDA is proposing to require in § 106.94(a) that manufacturers develop and follow a written audit plan that is available at the manufacturing facility for FDA inspection. A written audit plan is necessary to provide consistency in how audits are conducted and to ensure that the auditor can determine whether the facility is operating in compliance with the applicable procedures.

Proposed § 106.94(b) requires that the audit plan include the procedures that the manufacturer uses to determine whether the facility is operating in accordance with CGMP, with the applicable quality control procedures, and in a manner designed to prevent adulteration of the infant formula it produces. This proposed requirement derives from current § 106.100(j), which defines audit procedures as the methods used to review the manufacturing and quality control procedures and is intended to direct the manufacturer's attention to the fundamental goals of the manufacturing process in formulating its audit plan.

Proposed § 106.94(c) sets out the minimum requirements for the audit procedures that are to be employed by manufacturers. Under proposed § 106.94(c)(1) these procedures are to include a review of how the production and in-process control system established under § 106.6(b) is operating. In particular, proposed § 106.94(c)(1)(i) specifies that the evaluation of the production and in-process control system include observation of the production of infant formula and a comparison of the observed process to the written production and in-process control plan required under proposed § 106.6(b). FDA has tentatively concluded that such observations will show whether the production and in-process control system is being followed appropriately, and, if not, they will identify any deviations from the production and in-process control system, so that the manufacturer can take corrective actions to ensure that infant formula is produced in compliance with the production and in-process control system.

Proposed § 106.94(c)(1)(ii) requires that the evaluation of the production and in-process control system include a review of records of the monitoring of points, steps, or stages where control is deemed necessary to prevent adulteration. As discussed below, proposed § 106.100(e)(3) requires that the batch production and control records document the monitoring of all points where control is deemed necessary to prevent adulteration in the manufacturing of the batch. FDA has tentatively concluded that proposed § 106.94(c)(1)(ii) is necessary because the auditor can observe the production of only a limited number of batches of infant formula. A review of the production and in-process control records of all batches produced in a given period of time will ensure that the production and in-process control system is working appropriately on a continuous basis, will identify any point that monitoring reveals is out of control on a recurring basis, and will identify where the production and in-process control system needs improvement.

Proposed § 106.94(c)(1)(iii) requires that the evaluation of the production and in-process control system include a review of records of how deviations from any standard or specification at points, steps, or stages where control is deemed necessary to prevent adulteration were handled. As discussed below, proposed § 106.100(e)(4)(iii) requires that the batch records include the conclusions and followup of an investigation of the failure to meet any specification or standard at any point where control is deemed necessary to prevent adulteration. A review of these records as a part of the audit will identify failures that occur on a repeated basis and will show how these failures are handled by the manufacturer. The auditor will be able to evaluate whether the conclusions and followup of these investigations are appropriate for each failure to meet the specification or standard.

Proposed § 106.94(c)(2) requires that the audit procedures include a review of a representative sample of all records maintained in accordance with proposed § 106.100 (e) and (f). As discussed below, proposed § 106.100(e) sets out the requirements for the batch production and control records, and proposed § 106.100(f) sets out the requirements for records related to observance of CGMP. A review of a representative sample of these records will show the auditor whether there has been compliance with the appropriate regulations in producing the batches of product so that the formula is not adulterated. Section 412(b)(2)(B)(iv) of the act states that the audit is conducted to determine whether the manufacturer has complied with the regulations establishing CGMP for infant formulas, including quality control procedures. FDA has tentatively concluded that review of a representative sample of the records maintained in accordance with § 106.100 (e) and (f) is necessary to determine whether the manufacturer is complying with these regulations.

E. Quality Factors for Infant Formulas

1. What Are Quality Factors?

The agency is proposing to create a new subpart E to implement the quality factor requirements of sections 412 (a)(2) and (b)(1) of the act. Section 412(a)(2) of the act states that an infant formula is adulterated unless it meets the quality factor requirements that are established under section 412(b)(1). Section 412(b)(1) of the act states that the Secretary shall by regulation establish requirements for quality factors, including quality factor requirements for required nutrients for infant formulas to the extent possible consistent with current scientific knowledge. Therefore, it is incumbent on manufacturers to establish that the infant formula that they produce meets the minimum quality factor requirements that FDA adopts.

What Congress meant by ''quality factors'' is discussed in the report of the House Committee on Interstate and Foreign Commerce that accompanied the 1980 act. The report states that quality factors ''pertain to the bioavailability of a nutrient and the maintenance of levels or potency of nutrients during the expected shelf life of the product'' (Ref. 5). FDA, in proposed § 106.3(o), has defined ''quality factors'' in a manner that encompasses several basic concepts, including the concepts of

''bioavailability'' and of ''healthy growth.''

The concept of ''healthy growth'' was discussed in the report of the House Committee on Interstate and Foreign Commerce that accompanied the 1980 act. The report states that infant formulas are often the sole source of nutrition for infants, and that ''the growth of infants during the first few months of life often determines the pattern of development and quality of health in adult life'' (Ref. 5). FDA considers the concept of ''healthy growth'' to be broad, encompassing all aspects of physical growth and normal maturational development, including maturation of organ systems and achievement of normal functional development of motor, neurocognitive, and immune systems. All of these growth and maturational developmental processes are major determinants of an infant's ability to achieve his/her biological potential, and all can be affected by the nutritional status of an infant.

''Bioavailability'' of a nutrient for an infant means that the nutrient is physiologically available in sufficient quantities to perform its metabolic functions (Ref. 55). In a formula product, bioavailability of individual nutrients is affected by the net effect of the formulation and processing of the product on the chemical form of the nutrient. These processes are influenced by such factors as the chemical form of the nutrient in the ingredient source, the chemical form of the nutrient after processing, and the net effect of various inhibitors and enhancers in a food or meal on the chemical form of the nutrient and its ability to be absorbed and utilized by the infant. In the infant, the bioavailability of a nutrient is determined by the net effect of the amount of nutrient that is converted during digestion to an absorbable form, the proportion of the nutrient that is absorbed into the bloodstream, the proportion of the absorbed nutrient that is converted to its biologically useful form, and the proportion that is lost through excretory processes (Ref. 55). Bioavailability varies among nutrients within a given food product and, for a given nutrient, among foods. The factors affecting nutrient bioavailability are complex and can be difficult to predict based on analyzed nutrient values alone.

Bioavailability issues are particularly critical for infants during the first few months of life, where a single food (infant formula) serves as the sole source of all nutrients at a period when rapid physical growth and development and maturation of various organ systems makes the infant particularly vulnerable to harm by nutritional insults. Unlike the mixed diet of persons beyond infancy where poor bioavailability in one food can be compensated for by other foods in the diet, a problem with bioavailability in an infant formula affects the total amount of nutrient available to that infant for several months after birth. Furthermore, requirements for nutrients are higher per kilogram body weight during early infancy than at any other time during the life cycle. Because numerous critical developmental milestones (e.g., neurocognitive or immune functions) must be achieved by young infants, a nutrient insufficiency during infancy can quickly develop into serious, and in some cases, permanent adverse effects on a range of developmental processes, including physical growth and organ maturation. Thus, a problem with bioavailability is far more critical for a food such as infant formula than it is for foods that are used as part of a mixed diet by the general population.

Furthermore, the rapidly changing and increasingly complex physical, chemical, and biologically significant characteristics of ingredients used in new and reformulated infant formulas make it important to continually ensure that quality factor requirements are met. Changes in formulation of infant formulas are made by manufacturers for a variety of reasons, including enhancing the functional characteristics of the formula (e.g., to prevent separation of ingredients or to prevent clumping that will plug nipples on bottles), to enhance digestibility of the formula (e.g., different sources or blends of fats), or to improve the nutritional quality (e.g., a different source of protein or of a vitamin or mineral, or adding a nonrequired nutrient such as selenium). For example, in some formulas, novel sources of vegetable oils (e.g., fractions of plant oils that are particularly rich in certain types of fatty acids) have partially or fully replaced cow's milk fat as the fat source (Refs. 56 and 57). Whey proteins or highly processed proteins (e.g., hydrolyzed proteins) are now frequently used as partial or complete replacements for more traditional cow's milk protein sources. In other cases, nutrient/nutrient interactions (e.g., high iron inhibiting absorption of zinc) or nutrient/ingredient interactions (e.g., phytates from soy protein isolates inhibiting absorption of zinc, or the replacing of the milk sugar (lactose) that enhances absorption of calcium with a sugar source that does not have this ability) can adversely affect nutrient availability.

New processing methods may also have unintended consequences when used with established ingredients or formulations. For example, a new processing method that subjects the formula to conditions that are less denaturing to cow's milk proteins than traditional heat treatments could produce a formula that is less digestible and that causes reactivity of the gastrointestinal wall, such as has been seen with whole cow's milk (Ref. 58).

In summary, consideration of quality factors goes beyond analytical measures of the presence or absence of a nutrient in the formula product and is needed to provide assurance that adverse effects on the nutritional value of the formula for the infant do not unintentionally or unknowingly occur as a result of the formulation or the processing of an infant formula. Chemical analysis of the formula product to define its nutrient composition often overestimates the amount of nutrient that is bioavailable for physiological use by the infant. The quality factors, therefore, provide a means of evaluating whether a nutrient has become less bioavailable than would be expected, so that it is not sufficiently effective to meet its normal nutritive functions, or whether its bioavailability has been enhanced to a level that raises safety concerns.

Quality factor requirements are distinctly different from quality control procedures. While ''quality control procedures are intended to insure that the safety and nutritional potency of a formula is built into the manufacturing process'' (Ref. 5), quality factors are intended to ensure that an infant formula contains an adequate amount of each nutrient in a form that can be digested, absorbed, and utilized so that the infant's physiological needs for these nutrients will be met (Ref. 5). Changes in ingredient sources and processing can affect the chemical forms of nutrients in the formula product. Such changes can affect the digestion and absorption of food nutrients such that: (1) Absorption is incomplete, (2) absorbed nutrients are not in a form that allows use by metabolic pathways, or (3) the nutrient may interact with other dietary substances to cause excessive excretion. Thus, the amount of nutrients (i.e., the analyzable amounts) in formulas must generally be higher than the physiological requirements of infants (i.e., the amounts of nutrients needed by the body to meet metabolic and growth needs of infants). Although these inefficiencies are generally taken into account when recommending nutrient levels for infant formulas, there

is always the potential for affecting nutrient bioavailabilities in unexpected ways.

In summary, a demonstration that both the quantitative and quality factor requirements for essential nutrients in an infant formula are met is necessary to ensure that the infant formula is likely to meet all of the known physiological nutritional needs of infants and to ensure that healthy growth and nutritional well-being will be achieved by an infant consuming the infant formula as the sole source of nutrition.

2. Identification of Quality Factors

In testimony before the passage of the 1986 amendments, the agency informed the Senate that the state of knowledge and science with respect to quality factors was still evolving, and that, therefore, there was a basis for only one quality factor for a nutrient. (Although the testimony to the Senate does not specify the identity of the nutrient for which there was a basis for a quality factor, the quality factor was the protein efficiency ratio used for assessing protein quality (Ref. 1).) Senator Metzenbaum stressed that the amendments contemplated that additional quality factors would emerge, and that the Secretary should implement requirements for such factors as quickly as scientific advances would allow.

The agency subsequently took a major step toward establishing quality factors through a contract in 1986 with the CON/AAP. The AAP earlier had published recommendations regarding the quantities of nutrients needed in infant formulas (Ref. 59). These recommendations were relied upon during the development of the nutrient specifications of the act (Ref. 60). In its report to FDA, ''Clinical Testing of Infant Formulas with Respect to Nutritional Suitability for Term Infants'' (Ref. 6), the CON/AAP identified those conditions in which changes in formula composition warranted clinical testing. The CON/AAP stated that ''clinical testing is primarily useful for determining (1) acceptability of the formula, (2) ability of the formula to support normal growth, and (3) availability of selected nutrients.'' The CON/AAP also discussed the limitations of the available measurements, providing an assessment of the limits of scientific knowledge.

The agency has considered the CON/AAP report carefully and has also considered new scientific information published since the release of that report to determine what quality factors are appropriate for nutrients in infant formula. Based on its consideration, FDA is proposing to adopt § 106.96. This section, if adopted, will require that all infant formula be of sufficient quality that it meets the nutritional requirements of infants for healthy growth when fed as the sole source of nutrition, as indicated by a general quality factor for physical growth, assessed using anthropometric measures of infants consuming the formula, and by a nutrient-specific quality factor for protein biological quality, assessed by an animal bioassay using the formula.

The agency is not proposing to require that manufacturers measure, individually, the absorption, metabolism, metabolic transformation, or utilization of any of the other essential nutrients. These measures are often technically difficult or unavailable, difficult to interpret, or invasive, thus causing unnecessary testing of infants without potential for providing meaningful results. Rather, the agency has tentatively concluded that current scientific knowledge and ethical and practical considerations are supportive only of requiring two quality factor measures: (1) Physical growth of infants consuming the formula as an integrative indicator of the net effect of the overall nutritional quality of the formula, and (2) a rat bioassay of protein quality in the formula product to ensure that the infant's needs for individual amino acids will be met.

The agency has tentatively determined that these are minimum requirements. The agency recognizes that, on a case-by-case basis as warranted by the formulation and intended use of a particular infant formula, demonstration of additional quality factors may be necessary. For example, a formula intended for use by premature infants who are at a particularly vulnerable developmental stage relative to nutritional needs to support neurocognitive development may need to be subject to testing that includes measurement of this endpoint to ensure that the formula supports healthy growth. In addition, a formula in which a novel fatty acid has been added to enhance the formula's ability to meet nutritional needs for supporting visual development may need to be evaluated to determine whether it has adverse nutritional effects on other aspects of healthy growth (e.g., on development of immune function).

3. The Regulation

Proposed § 106.96(a) sets forth quality factor requirements that reflect the minimum measures needed to evaluate the nutritional quality of an infant formula product, taking into account current scientific knowledge and the usefulness of the outcome measures for evaluating quality factors, while minimizing unnecessary testing of infants serving as subjects in clinical trials. Infant formula is defined in the act as a complete or partial substitute for human milk (section 201(aa) of the act). Obviously, the greatest need for a nutritionally complete formula that meets all quality factors is when the formula is used as a complete substitute for human milk. When no other form of nutriture is available to the infant, the formula must provide all of the nutrients needed for the healthy growth of the infant. There is no room for error or miscalculation. The absence or an inadequate level of an essential nutrient will be evidenced by growth failure and other signs or symptoms resulting from nutritional insufficiencies. FDA has tentatively concluded, therefore, that an evaluation of the ability of a formula to support healthy growth must be made under its most demanding conditions of use, i.e., when it is used as the sole source of nutrition, because other foods may mask or compensate for deficiencies in the formula that would occur if the formula were used as a complete substitute for human milk, which would produce results that cannot be meaningfully interpreted.

Proposed § 106.96(b) identifies ''normal physical growth'' as a quality factor. This quality factor reflects the CON/AAP recommendation that the determination of physical growth rate is the most valuable component of the clinical evaluation of an infant formula (Ref. 6). Physical measures of growth such as weight gain are the most widely accepted and used markers of a young infant's overall ability to digest and utilize those nutrients provided by the formula. The very rapid rate of growth in early infancy means that abnormalities in growth rate can be detected in a few months, providing an easily measured and sensitive, although nonspecific, indication of nutritional insufficiencies (Ref. 4). Physical measures of growth rate are easily done, are familiar to both parents and health professionals, and are a normal part of routine office visits. They are noninvasive and pose little or no risk to infants and provide meaningful results for evaluating the ability of an infant formula to support physical growth in very young infants. Thus, the agency has tentatively concluded that the ability of the formula, when fed as a sole source of nutrition, to meet the nutritional requirements of young infants for normal physical growth is a

necessary indicator of the overall nutritional quality of the formula.

Proposed § 106.96(c) requires that the protein in infant formulas be of sufficient biological quality to meet the protein nutritional requirements of infants. Protein, while generally discussed as a single nutrient, depends for its nutritive value on the inclusion of all essential amino acids at levels and relative proportions needed to support healthy growth. The protein requirement is really the sum of different requirements for 10 essential amino acids that occur at different levels and proportions in various food protein sources. Protein quality is also affected by differences in digestibility of different protein sources, by factors that modify digestion, and by chemical reactions that affect the ability of enzymes in the infant's gastrointestinal tract to digest and absorb the amino acids in the protein source. Once absorbed, the relative proportions of the amino acids can affect their uptake by body tissues because of competition for receptors and transport systems. Thus, protein quality depends on a number of complex interactions and conditions that can be difficult to predict.

Chemical analysis of foods generally only measures the amount of total protein present and does not identify specific amino acids or their ability to meet the physiological needs of infants for the essential amino acids. Chemical analysis alone, therefore, is not capable of predicting whether adequate amounts of all essential amino acids are present, or whether the amino acids present are able to support healthy growth in infants. Yet ensuring that the protein in an infant formula's is of high biological value is critical to an infant's health. For example, during the first year of life, the protein content of an infant's body increases from 11 to 15 percent at the same time that the infant's body weight increases by 7 kg. The average increase in body protein is about 3.5 g/day for the first 4 months of life and about 3.1 g/day for the next 8 months. These protein requirements must be met by a formula that not only contains adequate protein but also contains protein of high biological quality in a form that can be utilized by the infant. Because biological quality varies among protein sources and may be adversely affected by processing methods and other constituents present in the formula, the agency has tentatively concluded that the biological quality of the protein in an infant formula is a necessary quality factor. This quality factor will require an evaluation of whether the formula contains the essential amino acids and total nitrogen in the amounts and proportions necessary to permit normal tissue and organ growth and development. As discussed later in this document, the agency is proposing in § 106.97(b) that the biological quality of the test protein be measured by the Protein Efficiency Ratio (PER) rat bioassay and be comparable to the biological quality of the milk protein casein.

Proposed § 106.96 does not include quality factor requirements for all nutrients required by infants because methods to determine whether these requirements are met are not available or are not practical for most nutrients (e.g., results cannot be meaningfully interpreted, or methods are invasive, thus causing unnecessary testing of infants). Nonetheless, FDA has tentatively concluded that, as the science evolves, establishing quality factor requirements for other nutrients needed by infants would provide assurance, beyond that provided by the general quality factor of physical growth in proposed § 106.96(b) and the specific protein quality factor in § 106.96(c), that a formula will meet the overall nutritional needs of infants. As the science evolves, FDA anticipates being able to progress beyond generalized, nonspecific indicators of overall nutritional intakes (e.g., measures of physical growth), to more specific and sensitive measures of biochemical and functional nutritional status. FDA also has tentatively concluded that, on a case-by-case basis, additional quality factors may be needed for a specific formula product if formulation or processing concerns raise sufficient quality factor questions such that additional measures are necessary to adequately ensure that the nutritional quality of the formula supports healthy growth. FDA asks for comment on criteria as to when such measures are required.

4. Request for Comment on Need for Establishing Requirements for Other Quality Factors

Proposed § 106.96(b) and (c) set forth minimum requirements for quality factors (physical growth and protein quality) that all infant formulas should meet. FDA has tentatively concluded that these quality factors are consistent with current state-of- the-art science and provide significant information on the nutritional quality of the infant formula without requiring unnecessary or meaningless testing of infant enrollees in studies.

As discussed above, the 1986 amendments contemplated that when scientific research identified criteria that could be used to establish quality factors for specific nutrients in infant formula, the agency would establish quality factor requirements for those nutrients. Proposed § 106.96 will establish two quality factors (physical growth and protein quality) because the agency has tentatively concluded that there is sufficient scientific evidence of the importance of these quality factors, and because adequate methods exist to meaningfully and ethically measure these factors.

However, the CON/AAP report discussed other nutrients necessary for healthy growth of infants and for which the report recommended establishing quality factor requirements (Ref. 6). The agency has studied the evidence supporting the establishment of quality factor requirements for these other nutrients, and the methods available for determining whether an infant formula meets quality factor requirements for these nutrients. FDA has tentatively concluded that establishing quality factor requirements for the three additional nutrients recommended by CON/AAP (i.e., (a) fat, as measured by fat balance; (b) calcium and phosphorus, as measured by calcium and phosphorus balance; and (c) iron as measured by iron bioavailability) is not warranted at this time. FDA, however, solicits additional information that it will consider before reaching a final decision on whether the scientific evidence and usefulness of results are sufficient to support establishing these additional quality factor requirements. Therefore, the agency requests comments and information on: (1) The scientific evidence on the importance of the amount, type, and sources of fat, calcium and phosphorus, and iron in infant formula, and (2) the appropriate methods and interpretative criteria to determine whether an infant formula meets the nutritional requirements for fat, calcium and phosphorus, and iron of infants consuming the formula as the sole source of nutrition. The basis upon which the agency is considering establishing quality factor requirements for these nutrients is discussed below.

a. *Fat.* The agency requests comment on a quality factor for fat balance that would require that all infant formulas be formulated and manufactured to provide fat in a manner that allows the fat to be absorbed and retained by infants at a level that the energy and other nutritional requirements of the infant are not adversely affected (Ref. 6). Normal, healthy, full-term infants fed various mixtures of the fats traditionally used in infant formulas in the United States rarely excrete more than 15 percent of their fat intake (Ref. 6). This level of fat excretion is an indication

that the fat is highly digestible. The use of a fat with lower digestibility would adversely affect energy balance, could reduce the absorption of fat-soluble vitamins and other nutrients, and could have a negative impact on healthy growth of the infants.

b. *Iron.* The agency solicits comment on a quality factor that would require that all infant formula be formulated and manufactured such that the iron used is bioavailable and meets the iron requirements of the growing infant. The maintenance of adequate iron status in the infant is important because iron is required to transport oxygen in the red blood cells to body tissues (as a component of hemoglobin), to supply oxygen to muscle tissue (as a component of myoglobin), and to support normal mental development. Full-term infants are generally born with adequate iron stores to meet their iron needs for the first few months of life, but the iron needs of premature infants and older infants must be met by the diet.

Iron bioavailability from infant formulas is low compared to the iron bioavailability from human milk (Refs. 61 and 62).

Nutrient sources and other ingredients, such as protein sources, can affect the chemical form of iron, thus interfering with its potential for absorption (Ref. 63). Furthermore, factors that enhance iron bioavailability from human breast milk are poorly understood and currently are not present in commercial formulas. Consequently, infant formulas are fortified with up to 10 times the amount of iron found in human milk. If, however, the bioavailability of the iron in the infant formula is substantially improved by a change in the formulation or processing of the formula, then reductions in the amounts of iron added to the infant formula may be necessary to prevent the infant from absorbing excessive amounts of iron which could be unsafe because high dietary intakes of iron can adversely interfere with the bioavailabilities of other nutrients (59 FR 51030, October 6, 1994). If, however, the iron was bound to another ingredient such that it interfered with absorption, the infant's physiological needs for iron might not be met. Infant formula iron levels and iron bioavailability, thus, represent a delicate balance between effectiveness and safety that cannot be adequately predicted by chemical analysis of the iron content of the formula, but can best be assessed by measurement of clinical indicators of iron status.

Early changes in iron nutritional status are not likely to be detected by the general quality factor of physical growth. Therefore, a quality factor requirement for an infant formula to meet the iron requirements of infants, and to contain sufficient bioavailable iron for this purpose, may be needed. The agency, however, is concerned that clinical studies, as described in proposed § 106.97(a), in which selection criteria include requirements that enrollees be healthy, full-term infants aged 0 to 4 and 5 months, may not be sensitive enough to detect significant differences in iron bioavailability of a formula product. Healthy, full-term infants are usually born with adequate iron stores to maintain normal iron status for the first 3 to 4 months of life—the period of time that a clinical trial would be conducted. Without assurance that the test results are meaningful, the agency has tentatively decided not to require a specific quality factor for iron bioavailability.

c. *Calcium and phosphorus.* The agency also requests comment on a quality factor that would require that all infant formulas be formulated and manufactured such that the calcium and phosphorus are bioavailable and meet the calcium and phosphorus needs of infants. Calcium and phosphorus are essential for healthy bone mineralization and growth in infants. Calcium bioavailability is of particular concern because inadequate intakes of calcium impair bone mineralization and can cause rickets in severe cases (Refs. 64 and 65).

Interactions with other ingredients and manufacturing processes can reduce calcium and phosphorus bioavailability. High concentrations of calcium and phosphorus can interact to form insoluble complexes that may be unavailable (Ref. 66). Calcium can interact with free fatty acids and form soaps that are not absorbed (Ref. 66). Lactose-free formulas have been found to have lower calcium absorption than formulas containing this sugar (Refs. 67 and 68).

Some phosphorus compounds, such as the phytates found in plant protein sources, may not be readily digested and absorbed by infants (Ref. 69). Inadequate dietary phosphorus can cause a loss of calcium from the body as a result of bone resorption (i.e., loss of bone mass) (Ref. 70). Formulation or processing changes that affect other formula ingredients that influence calcium and phosphorus absorption require careful consideration of their potential effects on calcium and phosphorus bioavailability and the calcium and phosphorus status of the infant.

A dietary insufficiency of calcium and phosphorus of a magnitude that decreases bone formation may not be detected by physical measures of growth (Ref. 71). Therefore, a quality factor requirement for an infant formula to ensure that it meets the calcium and phosphorous requirements of infants, and to ensure that it contains sufficient bioavailable calcium and phosphorus for this purpose, may be needed. FDA is concerned, however, that meaningful measures for assessing the bioavailability of calcium and phosphorus may not be available.

d. *Summary.* FDA has tentatively concluded that the clinical and nutritional sciences have not reached a state where specific tests are available that would permit manufacturers to establish that they meet quality factors for each of the essential nutrients listed in § 107.100, except for protein. Therefore, except for the quality factor requirements for physical growth and protein quality discussed above and set forth in proposed § 106.96 (b) and (c), the agency has tentatively concluded that it is not useful to propose quality factor requirements for specific nutrients at this time.

Thus, to meet the nutritional needs of infants consuming formula, manufacturers must use forms or sources of essential nutrients that are bioavailable. The agency is concerned that manufacturers could unintentionally or unknowingly use forms of nutrients that have a relatively low bioavailability or ingredients or processing methods that will produce interactions that adversely affect the bioavailability of nutrients, thereby adulterating the formula because it no longer meets the nutritional needs of the infant. However, at this time, FDA is not aware of a means to systematically identify those circumstances that could adversely affect all nutrient bioavailabilities. FDA does not believe that it is ethical to unnecessarily subject infants to testing protocols when meaningful results cannot be assured. However, because of the potential seriousness of the public health impact of not meeting quality factors, FDA also believes that it is desirable to establish additional quality factors, as soon as they are warranted by evolving scientific knowledge, to ensure adequate nutrient bioavailability.

FDA, therefore, requests comment on the: (a) Need for routine testing of quality factors, in addition to measures of physical growth and protein quality; (b) criteria to be used in determining that such a need can be meaningfully implemented, and (c) if a need is established, the type of qualitative and quantitative measurements that could be used by manufacturers to demonstrate

that an infant formula meets with those quality factors. If FDA receives information demonstrating the need for additional quality factors, it will consider including them in any final rule that results from this proceeding.

5. Assurances for Quality Factors

a. *Quality factor—physical growth of infants.* Proposed § 106.97(a)(1) requires that the manufacturer conduct an adequate and well-controlled clinical study to determine whether the formula supports normal physical growth in infants when it is fed as the sole source of nutrition. The CON/AAP Task Force on Clinical Testing of Infant Formulas (Ref. 6) concluded that the capability to support physical growth is the most widely accepted and used measurement available of the nutritional adequacy of an infant formula. Gains in weight and length of young infants reflect the long-term, integrative physiological processes that can only be achieved if the infant's nutritional needs are met.

A randomized, controlled study represents the most sensitive type of study to measure the nutritional adequacy of infant formula. The use of concurrent treatment and control groups is in agreement with the CON/AAP Task Force recommendations (Ref. 6) and with the agency's recommendations for human bioavailability studies of drugs (21 CFR 320.25). Although comparisons to historical controls (e.g., population reference standards) have been used by some investigators to evaluate growth of infants consuming a particular formula product, this type of study lends itself to misleading results because population reference standards are generally for the total population of infants (regardless of birth weight, health status, socioeconomic status, or other factors that can affect growth unrelated to nutritional components). In a study to evaluate the nutritional adequacy of a formula, on the other hand, selection criteria are usually used to limit enrollment to healthy, full-term infants. Thus, differences or similarities in growth between study infants and population reference standards cannot be meaningfully interpreted. Therefore, the agency is proposing to require that adequate and well-controlled clinical studies be conducted to collect the data needed to determine whether a formula satisfies the quality factor requirements for physical growth. To assist manufacturers in understanding the general principles for adequate and well-controlled clinical studies, FDA has prepared the ''Guideline for the Format and Content of the Clinical and Statistical Sections of New Drug Applications,'' U.S. Department of Health and Human Services, July, 1988 (Ref. 72).

FDA has tentatively concluded that it is necessary to enroll infants into a clinical study shortly after birth, and that the studies be at least 4 months in duration (see proposed § 106.97(a)(1)(i)(A)), to ensure that the study focuses on the period during which infant formula generally serves as the sole source of nutrition, and, thus, the infant is most vulnerable to a problem with a formula since the infant is not consuming other foods that could mask or compensate for a deficiency in the formula. Also, the sensitivity of growth studies for identifying nutritional problems with an infant formula is highest during early infancy. Young infants, those less than 4 to 5 months, allocate a substantially higher percentage of the intakes of energy, protein, and other nutrients for growth than do older infants. After this early period of rapid growth, the rate of physical growth slows, and the allocation of nutrient intakes for growth is lower. Thus, early infancy is the period of greatest nutritional risk and is the age associated with the most sensitive growth phase.

Because of the rapid rate of growth in infants less than 4 months of age, adverse nutritional impacts that affect growth rate can be detected within a few months (Ref. 4). Growth studies in older infants, where growth rates are of smaller magnitude and where solid foods are also consumed, are not sensitive enough to provide a meaningful evaluation of the ability of the formula to support healthy growth.

The CON/AAP Task Force (Ref. 6) also recommended that clinical studies be conducted for a period of 3 to 4 months, and that growth be examined at least during the first 8 weeks of life, because nutrient requirements per kg body weight are greatest during this period. It also pointed out that such a study will cover a period when the infant is not consuming solid foods, and the infant formula is fed as a sole source of nutrition.

Therefore, FDA has tentatively concluded that a clinical trial that lasts at least 4 months will be long enough to detect adverse effects of nutritional inadequacies on growth rate. FDA also has tentatively concluded that a clinical trial must be conducted with infants less than 1 month of age at the time of their entry into the study (see proposed § 106.97(a)(1)(i)(A)) to ensure that the formula is tested during the period of time when growth rate and nutrient requirements are proportionately greatest, and when the infant formula serves as the sole source of nutrition. These requirements are intended to ensure that the study assesses the nutritional adequacy of the formula for supporting normal physical growth in the young infant.

Under proposed § 106.97(a)(1)(i)(B), the manufacturer will be required to collect and maintain individual and group summary data on anthropometric measures of physical growth and plot the data on National Center for Health Statistics (NCHS) reference percentile body weight and body length curves, which are standard measurements of infant physical growth (Refs. 73, 74, and 75) and provide the most widely accepted assessment of infant growth (Ref. 6).

Plotting each infant's anthropometric data on NCHS reference percentile body weight and body length curves, and providing individual data on increments of weight gain, provide a means to make a quantitative assessment of the growth pattern over the 4 months duration of the study for individual infants. There is normally wide variation in body weights and lengths among healthy infants, with some being smaller than average and others average or above average. Single point measures of weight or length are difficult to interpret relative to a given infant because one does not know whether, for example, a smaller than average weight is attributable to inadequate nutrition or to a healthy and thriving infant whose body size is smaller than average.

Over time, young infants tend to individualize their track within a given percentile on population reference growth standards. An infant at the 25th percentile level for weight shortly after birth tends to stay at or near the 25th percentile for weight throughout the first few months of life. When multiple longitudinal measures of weight (or length) of an infant are plotted on a weight-for-age reference chart, a reviewer can make a quick assessment as to whether an infant's pattern of weight or length gain is similar to that expected for healthy infants of the same age, taking into account the range of normal individual variation in body weights and lengths and that infant's percentile track. Similar comparisons can be made with a given infant's weight or length incremental gain data relative to population reference standards. These data allow for identification of infants with unusually slow or rapid growth, an observation that is masked by grouped data.

Thus, plots of changes in individual infant's weight and length in conjunction with comparisons of increments per unit time of weight or length gains against population

reference standards allow researchers and reviewers to identify those infants whose growth is not following expected longitudinal patterns and, therefore, for whom a more thorough review of their medical and dietary histories is necessary to assess the possibility that the infant formula is responsible for reduced growth rates in a subgroup of infants. This careful review of individual infant growth patterns in addition to group summary data is particularly important because studies, while adequate to evaluate differences in group means between test and control formulas, often lack the statistical power to detect subgroups of infants whose growth patterns deviate from normal. These data will also provide useful information on possible trends towards failure to thrive or obesity, or on catchup growth in infants who experienced transient adverse effects relative to expected growth rates.

FDA has tentatively concluded that a comparison of a manufacturer's data to well-established population reference standards can provide the basis for an evaluation of the growth patterns of individual infants to identify, and to provide the basis for an investigation of, possible causes of unusually slow or fast rates of gain. Thus, the agency is proposing that the NCHS growth charts for individuals and for grouped data be incorporated by reference into the regulation (proposed § 106.97(a)(1)(i)(B)).

Proposed § 106.97(a)(1)(i)(C) requires that the manufacturer collect the anthropometric measurements at the beginning of the clinical study, at 2 weeks and at 4 weeks of the study, at least monthly thereafter, and at the conclusion of the study. These measurements will permit the calculation of incremental gains in the different measurements. Incremental gains, such as weight gain per unit of time, are generally considered the most sensitive indicator of the ability of a formula to support the physical growth of individual infants over time (Ref. 4). Also, because growth rate and nutritional requirements are curvilinear rather than linear during early infancy, multiple measurements help in assessing whether the formula meets the nutritional needs throughout the period of the clinical study and aids in more accurately placing infants in their ''correct'' reference percentile tract, particularly since age of enrollment varies somewhat among infants (although, if adopted, this regulation should serve to minimize that variation). Additionally, measures of an infant's body weight, the most critical anthropometric measure, are subject to a number of measurement errors unrelated to the nutritional value of the formula (e.g., timing of weighing of infant relative to feeding or defecation or urination).

For these reasons, multiple measures over a relatively long period (e.g., 4 months) provide a more accurate picture of the pattern of growth of infants than do one or two point measures. The agency has tentatively concluded that the requirement of four measurements taken 1 month apart will provide a sufficient number of measurements to permit evaluation of whether the formula meets the nutritional needs for physical growth of the infant throughout the study period. However, the agency requests comment, supported by data, on which measurements are needed to provide evidence that the formula meets the nutritional needs for physical growth of infants.

FDA has tentatively concluded that more frequent measurements are needed during the early stages of the study because variations in measured body weight that are a result of factors unrelated to the nutritional quality of the formula can be particularly serious in early infancy. For example, during the first week of life, there is a normal loss of body weight by the infant because of fluid loss that may reach 6 to 10 percent of body weight (Ref. 76). This weight loss will reduce the apparent growth of the infant as measured by body weight. This reduction may affect the ability to evaluate and interpret the weight gain data collected early in the study. FDA has tentatively concluded that requiring more frequent anthropometric measurements, especially for weight, early in the study, increases the ability to accurately place individual infants in the correct percentile track for monitoring their growth patterns in relation to the population reference curves and for monitoring physical growth during the most sensitive part of their growth phase.

To minimize the burdens of this regulation, FDA has not proposed to require that blood samples obtained from infants during the time period of their enrollment in the clinical study, or at completion of the study, be analyzed for biochemical and clinical indicators of nutritional and growth status. However, the CON/AAP Task Force (Ref. 6) recommended that some blood tests be conducted at the conclusion of required clinical studies to provide a more comprehensive evaluation of the nutritional adequacy of a formula. Thus, the agency requests comments on whether it would be useful for the manufacturer to collect and maintain data on standard laboratory measures, including complete blood count (white blood cell count and red blood cell count), hemoglobin concentration or hematocrit percentage, and serum or plasma concentrations of albumin, urea nitrogen, electrolytes (sodium, potassium, and chloride), alkaline phosphatase, and creatinine. These measurements are standard practice when infants are seen clinically and can be made with very small quantities of blood. The maintenance of these indicators within normal limits at the end of the study provides additional assurance over and above measures of physical growth that the infant's general state of well-being is healthy and ''normal,'' particularly because changes in biochemical measures may occur before detectable differences in physical growth are identified or may not be detected by measures of physical growth. General anthropometric measurements of physical growth provide indirect, although very important, evidence that the formula is able to help the infant maintain overall good health, but they are not as specific, and may not be as sensitive, as are biochemical indicators of health.

FDA also requests comment on whether requiring some, or all, of the biochemical and clinical tests described above would provide useful and necessary information for determining whether a formula causes adverse consequences that may not be reflected in the quality factor requirements for measurements of physical growth in proposed § 106.97(a)(1)(i).

The identification of deviations from expected values for these biochemical and clinical measurements, throughout the duration of the clinical study, could serve as an early warning of unexpected risk to infants enrolled in the study and, therefore, result in early actions to prevent undue risk to infant enrollees in the study. Conversely, collection of blood samples throughout the study could discourage parents from continuing their infants in the study, thus causing a high attrition rate and producing final study results that are difficult to interpret.

Proposed § 106.97(a)(1)(ii) sets forth guidelines for the design of clinical study protocols. A comprehensive clinical study protocol will ensure that individual investigators understand and follow generally accepted scientific principles for the design and conduct of clinical trials, thus enhancing the likelihood of interpretable results while maintaining minimal or no risk to infants enrolled in the studies. In the conduct of all studies, manufacturers should use the general principles,

described in § 314.126 (21 CFR 314.126) for adequate and well-controlled clinical studies to ensure that the design and conduct of the study are adequate to permit scientific review and interpretation of the study's results. Studies that cannot produce meaningful results because of poor or inadequate study design and conduct mean that infants will be subjected to unnecessary testing. Such a situation places infant enrollees at undue risk and is clearly unethical.

In this section, FDA is not establishing mandatory elements for inclusion in a protocol, nor requiring that manufacturers provide the agency with the protocol used for a study intended to provide data to show that an infant formula meets the quality factor requirements. However, as discussed above, a protocol is an essential part of the design and execution of a well-controlled scientific study. Furthermore, a protocol often provides invaluable information that assists in the analysis and interpretation of the study data. Consequently, the agency strongly encourages manufacturers to develop and use protocols that incorporate the specific elements in proposed § 106.97(a)(1)(ii) in all research studies using infants because these elements will ensure that the study is designed and conducted in a manner that will produce results that will permit meaningful evaluation of the usefulness of the infant formula.

The steps outlined in proposed § 106.97(a)(1)(ii)(A) represent standard practice in the design and conduct of clinical studies (Ref. 72). Proposed § 106.97(a)(1)(ii)(B) states that the clinical study protocol should describe the necessary qualifications and experience of the investigators. It is essential that clinical studies be conducted by personnel with sufficient experience and training to ensure that their work will yield interpretable and meaningful results. If a study is conducted by an investigator who is not qualified, it increases the likelihood that the study will have to be redone, and that more infants will be exposed to risk. Therefore, it is important that in the protocol, the manufacturer define the requisite qualifications to conduct the study it is designing.

Proposed § 106.97(a)(1)(ii)(C) states that the protocol should be reviewed and approved by an Institutional Review Board (IRB) in accordance with part 56 (21 CFR part 56), and that the manufacturer should establish procedures to obtain written informed consent from the parents or legal representatives of the infants enrolled in the study in accordance with part 50 (21 CFR part 50). These steps are necessary to protect the rights and safety of subjects involved in the studies.

Proposed § 106.97(a)(1)(ii)(D) states that the clinical study protocol should explain how the study population represents the population for which the new infant formula is intended. FDA has tentatively concluded that such an explanation is necessary so that if questions about the relevance of the study population arise, the answer is readily available and free of any taint that it is a post hoc rationalization. For example, FDA has recently had questions about a study that involved hospitalized infants that were offered to support use of the product on post-discharge infants. If there had been the type of explanation available that FDA is proposing in this guideline, it would have greatly minimized the questions about this product.

Proposed § 106.97(a)(1)(ii)(D) also states that the clinical study protocol should explain how the study addresses the intended conditions of use of the formula. FDA has tentatively concluded that, by having manufacturers consider this question before the study is conducted, this guideline will prevent clinical studies that are conducted under conditions of use that do not accurately reflect the proposed conditions of use. For example, a clinical study protocol for testing a formula designed to be used by premature infants throughout infancy should explain how the study design will provide information to support the claim that the formula supports healthy growth under these conditions.

Proposed § 106.97(a)(1)(ii)(E) states that the clinical study protocol should describe the sample size calculations and the power calculations and the basis for selecting the sample size and study design. This information is necessary to establish the likelihood that the study will not fail to detect a real difference, should there be a difference for the measurements of interest, between the infant formula being tested and the control. For example, a study might not find a difference in incremental rate of weight gain between infants consuming two formulas because too few infants were enrolled in the study to provide sufficient statistical power to detect this difference. Inadequate statistical power could mask the nutritional inferiority of a product and could result in the marketing of a formula that does not meet the quality factor requirements and, therefore, is not safe for its intended use. Therefore, FDA has tentatively concluded that this guideline is needed to ensure that manufacturers design their growth studies to be capable of detecting biologically meaningful differences for the endpoints of interest between the two formulas. Identification of differences would raise safety concerns or serious questions of nutritional quality of the test formula product.

Proposed § 106.97(a)(1)(ii)(F) states that the clinical study protocol should include a plan to identify and evaluate any adverse events. This proposed guideline is necessary to document that appropriate attention is given to the systematic evaluation and recording of any adverse events that may occur during the course of the study. Inadequate planning for and conduct of the monitoring of adverse events may result in an erroneous conclusion that the formula is safe and suitable, when in fact the formula is not safe and suitable for infants under intended conditions of use.

Proposed § 106.97(a)(1)(ii)(G) states that the clinical study protocol should describe the quality control procedures that the investigator will use to ensure the validity and reliability of the measurements collected. This proposed guideline represents standard practice in the design and conduct of clinical studies and is necessary to allow a meaningful interpretation of study results. Data obtained with unreliable measures, or with indicators that do not accurately or meaningfully measure identified endpoints, may produce misleading study results that are uninterpretable and that suggest that a formula is safe and suitable, when more valid or reliable measures would not have supported this conclusion. The institution of adequate quality control procedures before beginning a study provides a mechanism for manufacturers to ensure that the data collected are reliable, and that the study provides interpretable results.

Proposed § 106.97(a)(1)(ii)(H) states that the clinical study protocol should describe and compare the composition of the control and test formulas. These descriptions of the control and the test formulas are necessary to establish that the formula used as the control provides an adequate comparison for evaluating the quality factors of the test formula. If the control formula is not comparable to (i.e., bioequivalent to) formulas in current use, differences between the test and control formulas have no meaning. They cannot be generalized to projected conditions of use. For example, comparable or enhanced physical growth in infants consuming a test formula as compared to infants consuming a control formula when the control formula does not meet

requirements in § 107.100 for nutrients, or is not bioequivalent relative to quality factors to currently marketed formulas in the United States, cannot be interpreted as supporting healthy growth because it is not possible to determine whether the apparent ''equal'' or ''enhanced'' physical growth is attributable to the fact that the formula is nutritionally adequate, or whether the formula looks adequate because it is being compared to a nutritionally inadequate formula. The nature of the differences between control and test formulas will also affect sample size and measurement (endpoint) considerations.

FDA's experience in reviewing clinical data submitted with 90-day notifications has been that the absence of information on control formulas is not uncommon. Thus, FDA has tentatively concluded that a guideline on the information that needs to be considered in selecting a control formula is necessary to ensure that study results are meaningful and interpretable.

If the test formula used in a study is not identical to the formula that is intended to be marketed in the United States, proposed § 106.97(a)(1)(ii)(I) states that the clinical protocol should describe the basis upon which the manufacturer has decided that the test formula is appropriate for use in the study. This proposed guideline is necessary to ensure that the manufacturer considers such factors as the bioequivalence of the studied (test) formula relative to the formula that is to be marketed in this country and can document why its choice of test formulas is appropriate. Without this documentation, it would not be possible to determine whether the marketed formula meets the quality factor requirement in proposed § 106.96(b).

FDA has had experience under the 1986 amendments in which manufacturers have submitted data on test formulas that were significantly different (e.g., in calorie levels) from the formula that they intended to market as evidence of the safety and suitability of the latter formula. In these instances, the agency has had considerable difficulty in interpreting study results. Therefore, if the guidance in proposed § 106.97(a)(1)(ii)(I) is followed, this significant study design issue will be critically reviewed by manufacturers before they initiate their studies, and, as a result, they will be more likely to design and conduct a study that will produce data that can be meaningfully interpreted as evidence that an infant formula is safe, and that it supports healthy growth.

As provided in proposed § 106.97(a)(2), however, FDA recognizes, that while changes in ingredients or in the processes used in the manufacture of infant formulas can have a significant adverse impact on the levels or availability of nutrients that affect healthy growth of infants, other changes may not be likely to do so. In the latter circumstances, it may be possible to demonstrate that the quality factor requirements are met by means of measures or data that do not involve the use of clinical trials. If such assurances can be provided without clinical trials, then infants will not be subjected to unnecessary testing. Therefore, FDA sets out in proposed § 106.97(a)(2), the circumstances in which a manufacturer can request an exemption from the clinical study requirement.

Proposed § 106.97(a)(2)(i) provides for an exemption if the manufacturer can cite experience that shows that the ingredient, ingredient mixture, or processing method has been used to make an infant formula that meets the quality factor requirements in proposed § 106.96(a). For example, if the manufacturer has previously submitted information to FDA in response to the quality factor requirements of the act that showed that an infant formula that contains the ingredient or ingredient mixture, or that was produced by the processing method, in question supported adequate physical growth, this information could form the basis on which the new infant formula could qualify for an exemption from this quality factor requirement. Under this provision, FDA will evaluate the experience cited in support of an exemption on a case-by-case basis. FDA requests comment on this proposed provision.

Proposed § 106.97(a)(2)(ii) provides for an exemption if a manufacturer that markets a formulation in more than one form (such as liquid and powdered forms) can demonstrate that the quality factor requirements are met by the form of the formula that is processed using the method that has the greater potential for adversely affecting the formula's nutrient content and bioavailability. For example, the temperatures used to retort liquid formulas during processing can cause a loss of protein quality compared to powdered forms processed at lower temperatures (Refs. 77 and 78). Thus, if the liquid formula is tested and shown to meet the quality factors requirements, it will provide reasonable assurance that the powdered form of the formula, that is, the less processed form is of appropriate nutritional quality. Thus, FDA tentatively concludes that it would be unnecessary to test the less processed form.

Proposed § 106.97(a)(2)(iii) provides for an exemption if the manufacturer can demonstrate that the requirements of proposed § 106.97(a)(1) are not appropriate for the formula, and an alternative method or study design for showing that the formula supports healthy growth in infants fed the formula as a sole source of nutrition is available. As stated above, double-blind, well-controlled, clinical studies are generally the most powerful and sensitive method for demonstrating that an infant formula will support physical growth. Nonetheless, the agency anticipates that there will be circumstances in which a clinical study of a new infant formula would not be appropriate. For example, double-blind clinical studies would not be appropriate in situations such as those involving some exempt infant formulas in which they would cause withholding of conventional treatment and, therefore, would be unethical. Other situations that may not be amenable to double-blind clinical trials are those in which it would be difficult to enroll an adequate number of infants (e.g., for exempt infant formulas where the formula is intended for a rare disease). Alternative study designs may also be appropriate in situations in which a manufacturer has access to extensive reference data, such as a database on many similarly conducted clinical studies using infants from the same potential study population, provided that the manufacturer can demonstrate that the reference data apply to the new infant formula, its intended use, and its study population. FDA has tentatively concluded that such an exemption will permit flexibility in the design of suitable experimental protocols but still provide reasonable and documentable assurance that the study design can demonstrate the safety and suitability of the infant formula.

b. *Specific quality factors.* Proposed § 106.97(b) establishes requirements for demonstrating that a formula meets the protein quality factor requirement in proposed § 106.96(c) and requires that the manufacturer collect and maintain data that establish that the biological quality of protein in an infant formula is sufficient to meet the protein requirements of infants by demonstrating that the protein source supports adequate growth using the PER rat bioassay, which the agency proposes to incorporate by reference. The PER provides an estimate of the bioavailability and relative proportion of the essential amino acids in the protein-containing ingredient.

A chemical analysis of the protein can identify the amino acids contained in a protein source but does not measure their bioavailability. A protein source may contain the necessary amino acids, but they may be in a form that the infant cannot digest and absorb. Furthermore, processing methods may alter the chemical nature of the protein source, possibly making the protein more resistant to digestion by the infant. FDA has tentatively concluded that the rat bioassay is necessary to establish that the amino acids in a protein source are present, and that adequate amounts and proportions of all essential amino acids are capable of being digested by an infant. Such a showing is particularly important when a manufacturer is using a novel protein source (e.g., a hydrolyzed protein), a new protein mixture, a new processing method that could affect the chemical form or bonding of amino acids, or a formulation that provides an amount of protein near the minimum required level (<2.0 g/100 kilocalorie (kcal)) specified in § 107.100.

Proposed § 106.97(b)(1) also provides that if the manufacturer is unable to conduct a PER rat bioassay, it must demonstrate that the amino acid composition of the protein meets the known amino acid requirements of infants for whom the formula is intended. For example, FDA is aware that a PER would not provide useful data for an exempt infant formula intended for use in infants that cannot metabolize a specific amino acid and from which that amino acid has been purposefully omitted or is limited to a level inadequate to support healthy growth. The lack of that amino acid is necessary for the dietary management of the intended infant population but would result in an incomplete protein and would reduce the growth rate of the rat, invalidating the conditions upon which the PER rat bioassay is based. FDA is not aware of alternative methods for ensuring bioavailability of such a protein source. In these circumstances, proposed § 106.97(b)(1) will provide an alternate means of evaluating whether the protein at least contains adequate amounts of essential amino acids to meet the known amino acid requirements of the infant, even though the bioavailability of these amino acids cannot be assured using available methods.

Proposed § 106.97(b)(2) establishes the circumstances in which a manufacturer may request an exemption from the requirements of proposed § 106.97(b)(1). Proposed § 106.97(b)(2)(i) provides that if the protein source (including the processing method used to produce it) is already used in another of the infant formulas marketed by its manufacturer in the United States, the manufacturer may request an exemption if it can demonstrate that such other infant formula meets the quality factor requirements prescribed in § 106.96(b)(1). The purpose of the PER or amino acid analyses is to estimate the quality of the protein in the proposed formula. Once a manufacturer has established standard sources and processing of protein in a formula, and has demonstrated that the technology is effective, in its hands, in producing a formula that meets the quality factor requirement for protein, other formulation changes would not be expected to markedly affect protein quality. Thus, the quality of the processed protein would be retained in other formulas. However, under proposed 106.97(b)(2)(i), it will be incumbent on the manufacturer to demonstrate that the quality of the protein is not affected.

Proposed § 106.97(b)(2)(ii) provides for an exemption if the protein source, or the processing method used to produce the protein source, in the infant formula does not constitute a major change from the infant formula that it replaces, and the manufacturer can demonstrate that the infant formula that it replaces meets the quality factor requirements prescribed in § 106.96(b). FDA is proposing to allow this exemption because it is unlikely that the methods for assessing protein quality prescribed are sensitive enough to measure any change in protein quality that is not a major change.

Because FDA has, as a matter of policy, been requesting that infant formula manufacturers submit data from a PER or amino acid analysis as part of their submission 90 days prior to marketing infant formula, many infant formulas that are on the market have been shown to meet the proposed quality factor requirement for protein. Therefore, if the proposed exemption criteria in § 106.97(b)(2) are adopted, those formulas that contain protein sources, or proteins which were produced using processing methods, that were the subject of a submission to FDA in response to the quality factor requirements of the act may qualify for an exemption.

6. Request for Comment on Establishing Assurances for Other Quality Factors

As discussed above, FDA has solicited comment on whether to establish quality factor requirements for fat, iron, and calcium and phosphorus. If such quality factors are adopted, appropriate methods will be needed to provide assurance that an infant formula meets these nutrient-specific quality factors. Therefore, FDA discusses below measurements of fat balance and of calcium and phosphorus balance, as well as measurements that reflect iron bioavailability. The agency requests comments and information on these or other methods for these three quality factors:

a. *Apparent fat absorption.* Apparent digestibility and apparent absorption measure the amount of fat that was able to be digested and absorbed by the infant. Apparent digestibility is expressed as a percentage of intake, while apparent absorption is expressed in units of fat (e.g., g) absorbed per day. If a quality factor for fat were established, manufacturers would be required to collect and maintain data establishing that the apparent digestibility or apparent absorption by the infant of the fat in an infant formula is adequate to meet the infant's energy requirements. These data would be necessary because fat represents the major dietary source of energy for the infant and must be readily digested and absorbed if the formula is to support healthy growth.

The CON/AAP Task Force (Ref. 6) recommended that studies that are conducted to determine whether a formula meets the quality factor for fat should use a cross-over experimental design. This type of study requires that the manufacturer compare apparent fat absorption of infants fed the test formula at one time and a currently marketed formula at another time. An experiment using this design would enable a manufacturer to make measurements of apparent fat absorption using a small number of infants, since the variance in fat excretion of infants fed most fat sources currently available is less than 5 percent. Furthermore, the method is noninvasive, is easily implemented, and does not require costly or sophisticated equipment to conduct. Other experimental designs could be used but would require larger numbers of infants and would be more expensive. Thus, FDA asks for comments on whether there should be a specific requirement that manufacturers measure apparent fat absorption using cross-over studies.

The CON/AAP Task Force (Ref. 6) recommended that studies that are conducted to determine the apparent absorption of fat be conducted such that measurements are made using infants fed each formula for at least 72 hours. The Task Force report suggested that measurements of apparent fat absorption for this length of time would accurately reflect the apparent

absorption of the fat in the formula being tested. FDA is considering requiring that a study of at least 72 hours for each formula tested be conducted and requests comment on what duration would be appropriate. FDA also is considering whether to require that the manufacturer document the method that it used to analyze for fat and explain the reason for choosing that method. The agency believes that this information is important because the method used to analyze the excreted fat must be appropriate for the specific type of fat in the formula.

FDA also is considering whether circumstances exist that would justify establishing an exemption from the requirements to measure fat balance. FDA has tentatively concluded that the reasons and justification for such an exemption are essentially those set forth above in the discussion of proposed § 106.97(b)(2). FDA requests comment on whether, if the agency adopts a quality factor for fat, it should provide for exemptions from testing, to show that the formula meets that quality factor, such as those set forth in proposed § 106.97(b)(2), and to allow manufacturers to assure the agency that their products meet that quality factor requirement without subjecting infants to unnecessary testing.

b. *Calcium and phosphorus balance.* If FDA were to establish a quality factor for calcium and phosphorus, manufacturers would be required to collect and maintain data from clinical studies conducted in infants to show that the calcium and phosphorus contained in the infant formula are sufficient to meet the infant's requirements. There are currently no satisfactory clinical laboratory measurements that are practical for directly assessing calcium and phosphorus nutritional status in infants (Ref. 79). Furthermore, there are no accurate indirect measurements that could be made on the infant formula itself that would be useful in predicting how effective the amount and the sources of calcium and phosphorus in the formula would be in meeting the needs of infants consuming that formula. Therefore, FDA is considering requiring that manufacturers implement the recommendations of the CON/AAP Task Force and make a measurement that provides a reasonable estimate of the amount of calcium and phosphorus that is capable of being absorbed and retained for use by infants (i.e., calcium and phosphorus balance) from the formula.

FDA asks for comment concerning the appropriateness and usefulness of a measurement of calcium and phosphorus balance as one that reflects both the bioavailability of the calcium and phosphorus in the formula and how well the diet meets the metabolic requirements for these two minerals. As discussed above with regard to the conduct of trials to measure apparent fat absorption, FDA requests comment on whether it is necessary to require that a cross-over study design be used for clinical studies to measure calcium and phosphorus balance.

FDA also requests comment on what would be an appropriate duration for studies to measure calcium and phosphorus balance. The CON/AAP task force suggested that calcium and phosphorus balance studies be conducted for a 72-hour balance period after an 11-day adaptation period. FDA requests comment on whether these time periods are appropriate, both to minimize the effects of previous dietary intake on the availability of calcium from the formula being tested (Ref. 6) and to ensure that the results of the balance study are reliable and interpretable, and on whether they provide a meaningful basis on which to determine that a formula meets the quality factor requirement for calcium and phosphorus.

FDA is considering requiring that the formula used as the control in any clinical studies to measure calcium and phosphorus balance contain approximately the same calcium and phosphorus levels as the test formula because the absolute amounts of these nutrients absorbed and retained by infants may be different between formulas with different calcium and phosphorus levels. FDA is asking for comment on requirements for appropriate control formulas for calcium and phosphorus balance studies.

Amounts of calcium and phosphorus in urine and feces, along with calculated amounts absorbed and retained expressed in milligrams per kilogram and as percentages of intake, provide evidence of the rates of absorption and retention of these nutrients but do not specifically measure the ability of the formula to provide adequate calcium and phosphorus for proper bone mineralization, the most important need for these minerals in the infant. FDA is considering requiring that serum alkaline phosphatase be measured in situations in which calcium and phosphorus balance studies are required in order to assess the adequacy of formula minerals to support normal bone mineralization. Alkaline phosphatase is an enzyme involved in bone remodeling and in maintaining serum calcium concentration (Ref. 64). Increased serum alkaline phosphatase activity may be a marker of reduced bone mineralization (Ref. 80) and therefore may be useful in determining whether a formula meets a quality factor requirement for calcium and phosphorus.

Because of the limits of metabolic balance studies, including short duration, dependence on previous diet, and expense, the agency is considering the appropriateness of alternative methods for the assessment of bone mineral accretion. The agency is aware that sophisticated instruments, such as single-photon absorptiometry and dual-energy x-ray absorptiometry, have been tested for measuring bone mineral content in infants (Refs. 81 through 84), and that some authorities recommend them for determining bone mineralization in infants (Ref. 85). These types of measurements have the potential to provide an accurate measure of bone mineral accretion over the duration of use of the formula, while at the same time reducing many sources of variation inherent in balance studies. The agency is concerned, however, that these methods have not been adequately validated in infants, and that reference standards for mineralization in infants have not been established to support a requirement for manufacturers to measure bone mineralization in order to provide assurance that a formula satisfies a quality factor requirement for calcium and phosphorus. The agency asks for comment on the usefulness of these methods of analysis of bone mineral accretion in infants, and on whether they should be used in lieu of calcium and phosphorus balance studies as measurements of whether an infant formula meets the quality factor requirements for calcium and phosphorus assuming that the agency adopts such a quality factor. The agency also asks for comment on the criteria that it should use, on a case-by-case basis, in deciding whether to require these types of measures when there is particular reason to be concerned that calcium and phosphorus bioavailability may be problematic.

FDA also is considering whether circumstances exist that would justify establishing an exemption from a requirement to measure calcium and phosphorus balance. FDA has tentatively concluded that the reasons and justification for such an exemption are essentially those set forth above in the discussion of proposed § 106.97(b)(2), and requests comment on whether, if it adopts a quality factor for calcium and phosphorus, it should provide for exemptions from testing to show that the formula meets the quality

factor similar to those in proposed § 106.97(b)(2) and allow manufacturers to assure the agency that their products meet that requirement without requiring redundant testing.

c. *Iron status.* If FDA were to adopt a quality factor for iron, manufacturers would be required to collect and maintain data that establish that the iron in an infant formula is bioavailable and maintains the iron status of infants that consume the formula. These data would be necessary to demonstrate that an infant formula provides enough iron to prevent iron deficiency and anemia.

Alterations in a number of biochemical measurements are useful signs associated with inadequate iron intake or the development of iron deficiency. Early signs of inadequate iron intake, which reflect the depletion of iron storage sites, are reductions in serum ferritin concentration and transferrin saturation (Ref. 86). If the dietary intake of iron remains inadequate, impaired erythropoiesis (i.e., the process whereby the body produces new red blood cells) may be reflected in alterations in erythrocyte maturation and increases in erythrocyte size, erythrocyte protoporphyrin concentration, or serum transferrin receptor levels. If the period of inadequate iron intake continues, erythropoiesis is further impaired, and hemoglobin concentration, hematocrit, and mean corpuscular volume decrease.

Iron deficiency without anemia should be considered to be a risk factor for iron-deficiency anemia, which may be associated with long-lasting, adverse effects in infants (Ref. 86). Therefore, FDA is considering requiring one measurement of iron status that is sensitive to each of the three stages of inadequate iron intake (stage 1, decreased stores, normal erythropoiesis; stage 2, decreased stores and early stage impaired erythropoiesis; and stage 3, decreased stores and late stage impaired erythropoiesis). For example, FDA is considering requiring that manufacturers measure: (1) Serum ferritin concentration, because such a measurement is sensitive to decreased iron stores and normal erythropoiesis; (2) transferrin saturation or erythrocyte protoporphyrin concentration, because such measures are sensitive to decreased iron stores and early stage impaired erythropoiesis; and (3) hematocrit percentage, hemoglobin concentration, or mean corpuscular volume, because such measurements are sensitive to decreased iron stores and late stage impaired erythropoiesis. This approach would be consistent with the recommendations of the CON/AAP Task Force (Ref. 6). It would also provide reasonable assurance that low iron availability in an infant formula would be detected, and that an infant formula that does not provide sufficient iron to meet the infant's requirement, and thereby does not meet the quality factor requirement for iron, will not be marketed.

FDA also is considering whether circumstances exist that would justify establishing an exemption from the requirements to determine iron status. FDA has tentatively concluded that the reasons and justification for such an exemption are essentially those set forth above in the discussion of proposed § 106.97(b)(2). FDA requests comment on whether, if it adopts a quality factor for iron, it should provide for exemptions from testing similar to those set forth in proposed § 106.97(b)(2) to show that the formula meets that factor and allow manufacturers to assure the agency that their products meet that quality factor requirement without requiring redundant testing.

F. Records and Reports

1. Introduction

Under subpart C of part 106, FDA is proposing to revise the requirements on the records that must be made and retained. FDA is proposing requirements on batch records; records on CGMP and quality control procedures; maintenance of distribution records on formulas for export only; audits; and notifications to FDA. These proposed changes to current § 106.100 are outlined in Table III below:

TABLE III

Current Regulation	Proposed Regulation
§ 106.100(a)	No Change.
§ 106.100(b)	No Change.
§ 106.100(c)	No Change.
§ 106.100(d)	No Change.
§ 106.100(e), (f), and (h).	Current § 106.100(e), (f), and (h) will be incorporated into proposed § 106.100(e). New § 106.100(f) will codify the records required for the CGMP regulations found in proposed subpart B.
§ 106.100(g)	Current § 106.100(g) with modification.
§ 106.100(h)	Current § 106.100(h) is incorporated into § 106.100(e). § 106.100(h) Reserved.
§ 106.100(i)	No Change.
§ 106.100(j)	Current § 106.100(j) with modification.
§ 106.100(k)	Current § 106.100(k) with modification.
§ 106.100(l)	No Change.
§ 106.100(m)	No Change.
§ 106.100(n)	No Change.
§ 106.100(o)	No Change.

2. Batch Production and Control Records

Proposed § 106.100(e) requires that manufacturers make and retain records (hereafter referred to as ''batch records'') that include complete information relating to the production and control of each batch of infant formula. Section 412(b)(4)(A)(i) of the act requires the establishment, by regulation, of requirements for the retention of all records, including records containing the results of all testing required under section 412(b)(2)(B) of the act, necessary to demonstrate compliance with the CGMP requirements and quality control procedures prescribed under section 412(b)(2). In proposed § 106.100(e) FDA is proposing to require that manufacturers prepare and maintain records that include complete information relating to the production and control of the batch to ensure that the complete history of each batch of infant formula is available for review in the event that a problem arises with a particular batch.

Proposed § 106.100(e)(1) requires that the batch records include the appropriate master manufacturing order. As discussed above, proposed § 106.50(a) requires that manufacturers produce each infant formula in accordance with a master manufacturing order that has been approved by a responsible official of the company. The master manufacturing order thus provides fundamental information about the batch. Having all the information concerning the production of a batch of infant formula, including the master manufacturing order, in one place as a part of a batch record will ensure that there is a document available that makes readily apparent whether a batch was properly produced. It will also ensure that all the information needed to evaluate the cause of any problem that may develop with a batch of infant formula is readily available. Thus, FDA has tentatively concluded that the master manufacturing order is an essential part of the batch record.

Proposed § 106.100(e)(1)(i) requires that the master manufacturing order include the significant steps in the production of the batch of infant formula and the date on which each

significant step occurred. Thus, the master manufacturing order will include a list of the significant steps for the production of each infant formula and a space to write in the date the step was performed. Thus, it will provide both a check that the step was performed and a record of when it was performed. FDA has tentatively concluded that this information is necessary because all production activities for a specific batch of infant formula may not be accomplished in one day but may occur over a number of days, and people who begin work the second day will know what work has been completed, and what has not been. Moreover, each date is needed so that a batch of formula can be traced if, at a later date, a problem that may adversely affect an infant formula is identified at a specific production stage. Having the date available will allow the manufacturer to identify all batches that may have been affected by the problem.

Proposed § 106.100(e)(1)(ii) requires that, if the manufacturer has more than one line or set of equipment in the plant in which the formula is made, the master manufacturing order include the identity of equipment and processing lines used in producing the batch of infant formula. This information will allow the manufacturer to ensure that the equipment on which the formula was produced met the requirements of § 106.30. This information also will facilitate the identification of all batches of formula that may be affected by equipment malfunctions or that were produced on the same equipment as a batch that is discovered to be microbiologically contaminated.

Proposed § 106.100(e)(1)(iii) requires that the master manufacturing order include the identity of each batch or lot of ingredients, containers, and closures used in producing the batch of infant formula. All materials used in infant formula will have to meet the specifications of proposed § 106.40(d) and be identified by a batch or lot number as specified in proposed § 106.40(c). FDA has tentatively concluded that it is necessary to propose that the identity of each batch or lot of ingredients, containers, and closures used in producing the batch of infant formula be recorded in the master manufacturing order to enable the manufacturer to ensure that all of those materials met the requirements of § 106.40, particularly the standards for acceptance or rejection of the materials. Recording this information also will allow the manufacturer to evaluate the contribution of specific ingredients, containers, and closures to any problem with a batch of infant formula that may develop.

FDA is not proposing to require that the batch records contain the results of any tests conducted on ingredients, containers, and closures in accordance with proposed § 106.40(d) because the same lot of raw materials may be used in multiple batches. The identification of the batch or lot of all ingredients, containers, and closures in the master manufacturing order should be sufficient to allow the manufacturer to locate and review relevant test results if problems arise with a particular batch of infant formula.

Proposed § 106.100(e)(1)(iv) requires that the master manufacturing order include the amount of each ingredient to be added to the batch of infant formula and a check (verification) that the correct amount was added. As discussed above, proposed § 106.50(b) requires that the manufacturer establish controls to ensure that raw and in-process ingredients required by the master manufacturing order are examined by one person and checked by a second person or system to ensure that the correct weight or measure of the ingredient is added to the batch. The agency has tentatively concluded that recording in the master manufacturing order the amount of each ingredient added to the batch of formula, and a check (verification) that the correct amount was added, are appropriate controls to ensure that the correct weight or measure of the ingredient is added to the batch. This proposed requirement is necessary to ensure that there is compliance with proposed § 106.50(b), to provide a record that the batch of infant formula includes all of the ingredients in the amounts specified in the master manufacturing order, and to provide assurance that the product contains all of the required nutrients.

Proposed § 106.100(e)(1)(v) requires that the master manufacturing order include copies of all labeling used and the results of the examinations conducted during the finishing operations to ensure that containers and packages in the batch are correctly labeled. (The importance of ensuring that containers are correctly labeled was discussed in conjunction with proposed § 106.60(b).) The inclusion in the batch records of copies of the labeling used on each batch of infant formula will provide a record of such labeling and will document that the finishing operation examinations, required by proposed § 106.60(b), are conducted.

Proposed § 106.100(e)(2) requires that the batch record include any deviations from the master manufacturing order and any corrective actions taken. While the manufacturer's goal should be to produce the infant formula in accordance with the master manufacturing order, on occasion deviations may occur. On these occasions, the deviations, and any corrective actions taken because of the deviations, should become a part of the batch record. For example, if a batch of liquid infant formula was thermally processed at a different temperature than the temperature specified in the master manufacturing order, the batch record would state the actual processing temperature. The record would also state any corrective actions taken because of this processing temperature, such as a change in processing time. A record of deviations from the master manufacturing order and of the corrective actions taken by the manufacturer will allow the manufacturer to quickly determine whether all deviations have been appropriately addressed, and if they have not been, whether the actions needed to correct the deviations have been identified. It will also provide relevant information if a problem arises with that batch of infant formula.

Proposed § 106.100(e)(3) requires that the batch records include documentation of the monitoring at any production and in-process control point, step, or stage where control is deemed necessary to prevent adulteration. As discussed above, proposed § 106.6(c)(2) requires this monitoring. FDA is proposing that the documentation that the monitoring required by proposed § 106.6(c)(2) is occurring be included in the batch records to ensure that a measurement or observation made at one particular point in time can be related to a particular batch. The linkage of the record to the batch is especially important when a standard or specification is not met. It will enable the manufacturer to determine what batches may have been affected by a deviation and to take appropriate action, such as withholding a batch from distribution.

Proposed § 106.100(e)(3)(i) requires that the batch records include a list of the standards or specifications established at each point, step, or stage in the production process where control is deemed necessary to prevent adulteration, and that it include documentation of the scientific basis for each standard or specification. As discussed above, proposed § 106.6(c)(1) requires the establishment of such standards or specifications. The agency has tentatively concluded that a list of these standards or specifications must be a part of the batch record so that the manufacturer will have them readily

available to compare to the actual values obtained during the monitoring operation of the production and in-process control system. Also, the documentation of the scientific basis for each standard or specification will verify that each was established by trained and experienced sources. Such documentation will summarize the work performed to establish the standard or specification and will establish the source used. If changes to the standard or specification become necessary, this documentation of the scientific basis for each standard or specification will assist the manufacturer in making such changes.

Proposed § 106.100(e)(3)(ii) requires that the batch records include the actual values obtained during the monitoring (such as the actual temperatures and actual times that the measurements were taken), any deviations from the established standards or specifications, and any corrective actions taken. For example, notations that refrigeration temperatures are satisfactory or unsatisfactory, without a record of the actual temperatures, are subject to varying interpretation and thus will not ensure that preventive controls are working. It is important that the actual values be recorded. In addition, actual values are necessary to discern trends or to pinpoint the onset of a problem. The record of any corrective actions taken will show what the manufacturer did when a standard or specification was violated, and how the manufacturer is ensuring that the infant formula is not adulterated. Entry of information on the records at the time of the monitoring ensures that the record does not rely on the memory of the observer and thus is as accurate and valid as possible.

Proposed § 106.100(e)(3)(iii) requires that the batch records identify the person monitoring each point where control is deemed necessary to prevent adulteration. FDA has tentatively concluded that it is important that the responsible individuals be identified in the batch record so that the manufacturer can check that a qualified person is actually monitoring the point, step, or stage where control is deemed necessary to prevent adulteration, and so that such individual can be contacted if a problem with a batch of infant formula is identified at a later date. These individuals are in the best position to know of any other information that may not have seemed pertinent at the time but, in retrospect, could be important in identifying the cause of the problem and initiating actions to prevent it from recurring.

Proposed § 106.100(e)(4) requires that the batch records include the conclusions and followup, along with the identity, of the qualified individual who investigated any deviations, or failures to meet specifications, that occurred during the production of the batch. Under these proposed regulations, individuals qualified by training or experience must conduct an investigation of any deviation from the master manufacturing order and of the corrective actions taken (§ 106.50(a)(2)); conduct an investigation of a finding that a batch or any of its ingredients failed to meet any manufacturer's specifications (§§ 106.40(d) and 106.70(c)); and conduct an investigation of a failure to meet any specification or standard at any point where control is deemed necessary to prevent adulteration (§ 106.6(c)(4)).

FDA has tentatively concluded that the record of the conclusions and followup of these investigations is necessary to enable the manufacturer to ensure that it has complied with proposed §§ 106.6(c)(4), 106.40(d), 106.50(a)(2), and 106.70(c). Such records will provide information on how the production of the batch of infant formula deviated from established standards or specifications and on the cause of any problem with the formula, if infants are reported to have been adversely affected by the product at a later date. Identification of the qualified individual who conducted the investigations will ensure that there is responsibility and accountability for the investigation and will allow the responsible individuals to be contacted, if necessary. These individuals will be in the best position to provide information if additional details about the record are needed.

Proposed § 106.100(e)(5) requires that the batch records include the results of all testing performed on the batch of infant formula, including testing on the in-process batch, at the final-product stage, and on finished product throughout the shelf life of the product. Section 412(b)(2)(B) of the act requires that manufacturers conduct such testing. FDA has tentatively concluded that the assembly of such records in one place will enable the manufacturer to ensure that the batch of infant formula complies with proposed §§ 106.55 and 106.91 and will facilitate the review of the test results in the event that a problem arises with the batch.

Proposed § 106.100(e)(5)(i) states that the batch records are to include the results of any quality control testing conducted, in accordance with proposed § 106.91(a) and (b), to verify that each nutrient required by § 107.100 is present at the required level, and that any nutrient added by the manufacturer is present at the appropriate level. Including the results of this testing in the batch records will provide data needed to evaluate compliance of the batch of infant formula with proposed § 106.91, and provide data needed to evaluate a batch of infant formula if problems, such as adverse events in infants, occur later with that particular batch. These records will show the levels of nutrients in the formula and will provide information to help the manufacturer determine whether any problems associated with the formula are attributable to the nutrient levels in the product.

Proposed § 106.100(e)(5)(i)(A) requires that manufacturers maintain a summary table in the batch record that identifies the stages of the manufacturing process at which the nutrient analysis is conducted for each nutrient, in accordance with proposed § 106.91(a). As discussed above, proposed § 106.91(a) provides flexibility in the stage at which many of the nutrients are tested. A summary table will facilitate the manufacturer's compliance with quality control procedures because it will allow a manufacturer to quickly verify that it has tested for all the nutrients required by § 107.100 during the production of the infant formula.

Proposed § 106.100(e)(5)(i)(B) requires that the quality control records in the batch record include a summary table on the stability testing program, conducted in accordance with proposed § 106.91(b), including the nutrients tested and the frequency of testing of nutrients throughout the shelf life of the product. As discussed above, proposed § 106.91(b) requires that manufacturers test infant formula at the beginning, midpoint, and end of the shelf life, and with sufficient frequency to ensure that the manufacturer is aware if there is a significant deterioration in the required level of a nutrient. Therefore, proposed § 106.91(b) provides flexibility in the testing frequency, depending on the shelf life and the characteristics of the product. A summary table will facilitate the manufacturer's compliance with quality control procedures because it will allow a manufacturer to quickly determine whether it has tested for all the nutrients required by § 107.100 with sufficient frequency to verify that the ''use by'' date on the formula is appropriate.

Proposed § 106.100(e)(5)(ii) requires that the batch records for powdered infant formula include the results of any testing conducted in accordance with proposed § 106.55(b) to document that the tests were done and to verify compliance with the microbiological

quality standards in proposed § 106.55(c). As discussed above, proposed § 106.55(b) requires that manufacturers test representative samples of each batch of powdered infant formula to ensure that the batch meets the microbiological quality standards in proposed § 106.55(c) and therefore is not adulterated. This record will also provide the manufacturer with data to evaluate adverse events that infants may have experienced after consuming this batch of infant formula by showing whether microbiological contamination could have contributed to the adverse event.

3. CGMP Records

Proposed § 106.100(f) identifies the records that manufacturers must make and retain pertaining to CGMP described in proposed subpart B of part 106. Section 412(b)(4)(A)(i) of the act requires the establishment by regulation of requirements for the retention of all records necessary to demonstrate compliance with the CGMP, including testing designed to prevent the adulteration of infant formula. FDA has already discussed proposed regulations (proposed § 106.100(e)) respecting the retention of records relating to each batch of infant formula. FDA also is proposing regulations respecting the retention of records relating to the overall operation of the plant and the maintenance of equipment, because these records are necessary to demonstrate that the infant formula was manufactured in a manner designed to prevent adulteration. Maintenance of these records will help manufacturers identify trends in the processing of the infant formula, in particular trends that show when the process is breaking down in a way that will lead to the production of adulterated product. These records also will provide information to assist the manufacturer in tracking the cause of adverse events to a formula, if such events are reported.

Proposed § 106.100(f)(1) requires that manufacturers make and retain records of the frequency and results of the testing of water used in the production of infant formula. These records will show if problems are starting to develop with the water supply so that manufacturers can take corrective actions before the water is inappropriate for use in infant formula.

Proposed § 106.100(f)(2) requires that manufacturers make and retain records, in accordance with § 106.30(d), of accuracy checks on instruments and controls. Under this proposal, these records must include a certification of the accuracy of any known reference standard used and a history of its recertification. As discussed previously, the accuracy of the reference standard must be ensured before it can be used to ensure that the production instruments are properly calibrated. These records also will provide information to assist the manufacturer in tracing the source of a problem, if one arises, with a batch of infant formula. For example, if infants have adverse events to a batch of infant formula, records containing a certification of accuracy of the reference standards used and a history of their recertification would assist the manufacturer in determining whether the problem was created because a production instrument was calibrated with an inaccurate reference instrument.

FDA is proposing to require that, at a minimum, the records specify the instrument or control being checked, the date of the accuracy check, the standard used, the calibration method used, the results found, any actions taken if the instrument is found to be out of calibration, and the initials or name of the individual performing the test. These records will enable the manufacturer to determine, based on the performance of the instrument, whether the calibration schedule is sufficient to ensure the accuracy of the instrument. These records also will provide information on when and how the instruments were calibrated to assist the manufacturer in identifying the cause of a problem, if one arises, with a batch of infant formula.

Including the date of the accuracy check in the record will permit a determination of the accuracy of the instrument or control over time; including the standard used will allow the manufacturer to verify that the standard was properly calibrated; and including the calibration method used will ensure that the instrument is being calibrated free from the variability that can occur when different laboratory personnel perform the same calibration. The results of the accuracy check in the record will show whether the instrument or control is accurate, or whether a correction was necessary. Documenting the actions taken if the instrument is found to be out of calibration will enable the manufacturer to ensure that a correction was made. Requiring that the individual performing the test note his or her initials or name in the record will document who was last responsible for ensuring the accuracy of the instrument or control and will allow the manufacturer to discuss questions that may arise about the record with the person in the best position to know additional, but unrecorded, details about the record.

If calibration of an instrument shows that a specification or standard, at a point, step, or stage in the production process where control is deemed necessary to prevent adulteration, has not been met, a written evaluation of all affected product, and of any actions that need to be taken with respect to that product, needs to be made. For example, if the manufacturer is monitoring temperature to ensure that a specification or standard of 250 °F is maintained as a minimum temperature, and calibration of the temperature indicating instruments against a reference standard reveals that it was reading a true temperature of 248 °F, an evaluation of the health hazard significance of this temperature deviation must be made. This proposed requirement is necessary because, if an instrument is found to have been giving inaccurate readings, all infant formula produced subject to such inaccuracies must be identified and evaluated for the possibility that the inaccuracies caused the formula to be adulterated. In identifying the affected product to ensure that the health of potentially affected infants is fully protected, in the absence of evidence to the contrary, such evaluation would cover all product manufactured since the last time the instrument was calibrated and found to be accurate.

Proposed § 106.100(f)(3) requires that manufacturers make and retain records, in accordance with proposed § 106.30(e)(3)(ii), of the temperatures monitored for cold storage compartments and thermal processing equipment. These records are needed to show that the thermal processing equipment or cold storage compartments are being maintained at the correct temperatures to prevent adulteration of the product. The records of these temperatures will enable the manufacturer to identify trends in temperature fluctuations that can signal the need to perform nonscheduled maintenance.

FDA is proposing in § 106.100(f)(4) that equipment cleaning, sanitizing, and maintenance records, showing the date and time of maintenance, as well as the lot number of each batch of infant formula processed between equipment startup and shutdown for cleaning, sanitizing, and maintenance, be made and maintained. These records will allow the manufacturer to ensure that equipment and utensils are being cleaned and maintained regularly and to check that the frequency of such cleaning, sanitizing, and maintenance is appropriate in light of the actual, as

opposed to planned, use of the equipment. For example, a manufacturer may need to increase the frequency of cleaning, sanitizing, and maintenance if actual rate of production consistently exceeds the predicted rate of production. These records also will allow the manufacturer to trace all formula that may be affected if evidence becomes available that a particular cleaning, sanitizing, or maintenance was improperly performed.

Proposed § 106.100(f)(4) also requires that the person performing and checking the cleaning, sanitizing, or maintenance date and sign or initial the record indicating that the work was performed. Identification of the person performing and checking the cleaning, sanitizing, or maintenance will allow the manufacturer to ensure that a qualified person is doing these tasks and to discuss questions that may arise about the record with the person in the best position to know additional, but unrecorded, details about the record.

Proposed § 106.100(f)(5) requires that manufacturers make and retain records, in accordance with § 106.35(c), on all automatic (mechanical or electronic) equipment used in the production or quality control of infant formula. Proposed § 106.100(f)(5)(i) requires that the automatic equipment records include a list of all systems used, with a description of computer files and of the inherent limitations of each system. The manufacturer cannot effectively operate the system, and correct problems that arise, if it does not understand the system. It is not always possible for the individuals who developed and best understand the system to be present when the system is operating. Therefore, these records will enable the manufacturer to operate and troubleshoot the systems even when the individuals who best know the system are not available.

Proposed § 106.100(f)(5)(ii) requires that the automatic equipment records include a copy of all software used. Having a copy of all software used will minimize the manufacturer's down time if problems occur, and parts of the software are lost from the system. For example, if a computer virus is found in the software used to run the processing lines, having a copy of the software to reload into the hardware will minimize the time lost. Likewise, if there is a problem with the software used to perform quality control testing, having copies of this software will ensure that the testing can continue with a minimum amount of time lost.

Proposed § 106.100(f)(5)(iii) further requires that the automatic equipment records document installation, calibration, testing or validation, and maintenance of the systems used. These requirements are necessary for compliance with section 412(b)(4)(A)(i) of the act. As discussed more fully above with respect to proposed § 106.35 (b)(1), (b)(2), and (b)(4) CGMP requires that all systems be installed, calibrated, and maintained in a manner necessary to ensure that they are capable of performing their intended function and of producing or analyzing infant formula as intended, and that all systems be validated before their first use to manufacture commercial product. In addition to documenting that the manufacturer is complying with CGMP, records documenting installation, calibration, testing or validation, and maintenance of systems are necessary to provide information if the manufacturer later tries to determine why a problem with the system is occurring or tries to determine why the system is not producing an infant formula that complies with the manufacturer's specifications for the product.

Proposed § 106.100(f)(5)(iv) requires that the automatic equipment records include a list of all persons authorized to create or modify software. This record will help to minimize delays when the name of a person with those skills is needed quickly.

Proposed § 106.100(f)(5)(v) requires that the automatic equipment records document modifications to software, including the identity of the person who modified it. This documentation will ensure that the manufacturer is aware of any changes made to the software, and that it has a record of how the changed system works, so that it can continue to operate the system even in the absence of the responsible individual who made the modification to the system. A record of the identity of the person who modified the software will show who was responsible for modifying the software if problems arise with the operation of the system and will identify the person in the best position to know additional, but unrecorded, details about the software modification to help in troubleshooting the software problems.

Proposed § 106.100(f)(5)(vi) requires that the automatic equipment records include documentation of retesting or revalidation of modified systems. This proposed requirement is necessary for compliance with section 412(b)(4)(A)(i) of the act. As discussed more fully above in the section on proposed § 106.35(b)(5), CGMP requires that all modifications to software be made by a designated individual, and that all systems be revalidated after any modification to ensure that infant formula produced or analyzed using the modified software complies with subparts B and C. FDA has tentatively concluded that records on retesting or revalidation of the modified systems, just like records on the initial testing or validation of the system (§ 106.100(f)(5)(iii)), are necessary to document that the work has been done properly and to provide information if the manufacturer later tries to determine why a problem with the system is occurring or tries to determine why the system isnot producing an infant formula that complies with the manufacturer's specifications for the product.

Proposed § 106.100(f)(5)(vii) requires that the manufacturer make and retain a backup file of data entered into a computer or related system. It also requires that this backup file consist of a hard copy or alternative system, such as duplicate diskettes, tapes, or microfilm, designed to ensure that backup data are exact and complete, and that they are secure from alteration, inadvertent erasures, or loss. This proposed requirement is necessary to ensure compliance with CGMP because computer files can be easily altered or erased. Backup files of data will allow the manufacturer to readily reload the files of data if problems occur in the operation of the computer or related system, so that the manufacturer's down time is minimized, and so that the data entered into the system will be an exact copy of the data previously used in the system.

Proposed § 106.100(f)(6) requires that manufacturers make and retain records on ingredients, containers, and closures, including the identity and quantity of each lot, the name of the supplier, the supplier's lot number, the name and location of the manufacturer (if different from the supplier), the date of receipt, and the receiving code as specified (proposed § 106.100(f)(6) (i) through (vi)). These records will enable the manufacturer to document that it is complying with proposed § 106.40(g). Moreover, this information is needed to enable the manufacturer to track the source of each ingredient, container, or closure used in infant formula if a problem arises. If an ingredient, container, or closure is found to cause adulteration of the formula, it is important to be able to determine the source of the material, so that use of such materials can be halted and prevented in the future.

Proposed § 106.100(f)(6)(vii) requires that the records on ingredients, containers, and closures include the results and conclusions of any test or examination, including retesting and

reexamination, performed on them and their disposition. These records will document that appropriate testing is being conducted to ensure that the ingredients will not adulterate the infant formula, and that the containers and closures will protect the infant formula against adulteration. Further, these records will show the basis on which each ingredient, container, and closure was released for use in infant formula production if questions about such release later arise. Individual lots of ingredients, containers, and closures are likely to be used in a number of different batches of infant formula; therefore, the agency is proposing that the records on ingredients, containers, and closures be a part of the records pertaining to CGMP. Retaining such records in the CGMP records, rather than in each batch record, will eliminate the duplication of records and simplify the recordkeeping. The disposition of the ingredients, containers, and closures will show which materials were destroyed because they did not meet the manufacturers specifications (and not used in manufacture in compliance with § 106.40(d)), and which batches of infant formula were made using each lot of ingredients, containers, or closures. Thus, the manufacturer will know which lots of ingredients, containers, or closures were used in making infant formula and will be able to confirm that those lots complied with proposed § 106.40(d). Moreover, if a batch of formula is shown to be adulterated, these records will help the manufacturer to identify the source of the adulteration.

Proposed § 106.100(f)(7) requires that manufacturers make and retain records that include a full description of the methodology used to test powdered infant formulas to verify compliance with proposed § 106.55(c) and the methodology used to conduct quality control testing in accordance with § 106.91 (a) and (b). The agency has not specified in these regulations the methodologies that must be used to conduct microbiological and quality control testing. Thus, FDA has tentatively concluded that a manufacturer needs to maintain a record that fully describes the methodology that it has decided to use to test powdered infant formula for microorganisms and for quality control testing. Such a record is necessary if there is to be consistency in the procedure that the manufacturer follows in testing each batch of infant formula, particularly in light of the fact that the laboratory personnel conducting the testing are likely to vary. The accuracy and reproducibility of microbiological and quality control testing depend on the procedure used to conduct the test.

FDA is proposing that the full description of the methodology be retained as part of the CGMP records, rather than in the batch record provided for in proposed § 106.100(e)(5), because these methods will be used to test multiple batches of infant formula. Retaining such records in the CGMP records, rather than in each batch record, will mean that the manufacturer has to maintain only one document, rather than having to reproduce it each time that it runs a batch of formula. Thus, the proposed approach will eliminate duplication of records and simplify recordkeeping.

4. Records on Distribution of Infant Formulas

Proposed § 106.100(g) adds to current § 106.100(g) a requirement that records pertaining to distribution of the infant formula show that products intended for export only are in fact exported. It has recently come to the attention of the agency that infant formulas produced for export have been diverted and sold in the United States. All persons introducing any new infant formula into interstate commerce, which includes persons exporting an infant formula to a foreign country, are required by section 412(c) of the act to register and make a submission to the agency 90 days before marketing the formula. (See discussion of proposed §§ 106.110 and 106.120.)

As discussed in the section of this preamble on proposed § 106.120(c), the agency has tentatively concluded that it will not require manufacturers who produce infant formula for export only to submit the same information that would be required for products intended or offered for sale in the United States. In lieu of the information required by § 106.120(b), FDA is proposing to allow manufacturers of products for export only to give assurances that the infant formula will not be sold or offered for sale in domestic commerce. This provision is based, in part, on section 801(e) of the act, which states that a food will not be deemed to be adulterated or misbranded under the act if, among other things, it is not sold or offered for sale in domestic commerce. Thus, the agency has tentatively concluded that the additional recordkeeping requirement on distribution of infant formulas for export only in proposed § 106.100(g) is necessary so that verification that the infant formula was not in fact sold or offered for sale in domestic commerce will be readily available in the manufacturer's records.

5. Audit Records

Proposed § 106.100(j) carries forward the requirement in current § 106.100(j) that the manufacturer make and retain records, which include the audit plans and procedures, that pertain to regularly scheduled audits. As discussed above, the written audit plan, which includes audit procedures, is required under proposed § 106.94(a) and (b). The proposed section further requires that records of audits include the findings of the audit and a listing of any changes made in response to these findings. This requirement is proposed under the authority of section 412(b)(4)(A)(v) of the act, which requires that manufacturers retain all records of the results of regularly scheduled audits conducted under the requirements prescribed by the Secretary (and by delegation, FDA) under the authority of section 412(b)(2)(B)(iv).

Proposed § 106.100(j) also requires that the manufacturer make readily available for authorized inspection the audit plans and procedures and a statement of assurance that the regularly scheduled audits are being conducted. This provision implements section 412(b)(4)(B)(ii) of the act, which requires that the manufacturer provide written assurance that the regularly scheduled audits are being conducted by the manufacturer. However, proposed § 106.100(j) also provides that the findings of the audit and any changes made in response to these findings need not be made available to FDA. This provision is brought forward from current § 106.100(j) and reflects section 412(b)(4)(B)(ii) of the act, which states that a ''manufacturer need only provide written assurances to the Secretary that the regularly scheduled audits required by'' section 412(b)(2)(B)(iv) of the act ''are being conducted by the manufacturer, and need not make available to the Secretary the actual written reports of such audits.''

6. Modification of Current § 106.100(k)(3)

The agency also is revising current § 106.100(k)(3) to reflect the numbering changes in the regulations on notifying the agency of a causal relationship between the consumption of an infant formula and an infant's death. The agency is moving the requirements of current § 106.120(b) to § 106.150 to reflect the changes it is proposing in subpart G. Thus, the reference to § 106.120 in § 106.100 (k)(3) will be changed to read ''§ 106.150,'' if the

agency adopts the relevant proposed changes.

G. Registration, Submission, and Notification Requirements

1. Introduction

The act provides for three types of notices that manufacturers of infant formula must provide to FDA and sets forth the general information that must be included in each type of notice. First, manufacturers of a new infant formula must register with FDA, in accordance with section 412(c)(1)(A) of the act, providing the name and address of the firm and all establishments that will manufacture the new infant formula. Second, manufacturers must submit to FDA, in accordance with section 412(d) of the act, certain information concerning a new infant formula or an infant formula in which there is a change in formulation or processing that may affect whether the formula is adulterated under section 412(a) of the act. Third, manufacturers must notify FDA, in accordance with section 412(e) of the act, of any adulterated or misbranded infant formula that has left their control.

The agency has not specified the information that must be included in an infant formula registration, submission, or notification. While firms have been able to function under these requirements since the 1986 amendments were enacted with respect to the notice that manufacturers must provide to the agency under section 412(c) and (d) of the act, inquiries from industry suggest that manufacturers are uncertain about the information that they must provide. Some manufacturers have needed to make multiple submissions for a new infant formula because of deficiencies in the initial submission. For example, some submissions have contained information concerning more than one formula without clearly identifying which information applied to which formula. Some submissions have not contained the information required by section 412(d)(1) of the act. Therefore, FDA recognizes that it will be useful both to manufacturers and to the agency to issue regulations to ensure that registrations and submissions required by the act follow a consistent format and contain the necessary information for the agency to determine whether there is a basis to object to the marketing of a new infant formula. Such regulations will facilitate the manufacturer's preparation of the notice and also will facilitate the agency's review of the notice once FDA receives it.

These proposed regulations also will make clear when a registration, notification, or submission to the agency is needed. For example, as stated above, it has recently come to the attention of the agency that some firms that manufacture infant formula intended only for export are not aware of their registration and submission responsibilities. Section 412(c)(1) of the act requires that a person introducing a new infant formula into interstate commerce (which includes export to a foreign country) must register the infant formula and make the proper submission 90 days before marketing it. These proposed regulations make clear that registration and submission requirements apply to infant formulas intended only for export as well as to infant formula intended for the domestic market.

Finally, for completeness, FDA has decided that it would be useful to both manufacturers and the agency, to carry forward current § 106.240, concerning notification of a violative infant formula, as § 106.150. Doing so will consolidate in one place in the agency's regulations all requirements concerning notice to the agency to meet the requirements of section 412(c), (d), and (e) of the act.

2. New Infant Formula Registration

Proposed § 106.110(a) requires that a manufacturer of a new infant formula register with FDA before introducing the formula, or delivering it for introduction, into interstate commerce. Because ''interstate commerce'' is defined in section 201(b) of the act as ''(1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body,'' under this provision, a manufacturer is required to register with FDA before introducing a new infant formula into the United States market or before beginning exporting the formula. Proposed § 106.110(a) sets out how to comply with section 412(c)(1)(A) of the act. Failure to provide the notice required by section 412(c)(1)(A) of the act is a prohibited act under section 301(s).

Under section 412(c)(1)(A) of the act, proposed § 106.110(b) sets out the information required in a new infant formula registration. While manufacturers may register at any time before introducing a new formula into interstate commerce, FDA urges that they do so at the same time that they submit notice of their intent to market a new infant formula in accordance with section 412(c)(1)(B) and (d)(1) of the act. Receiving registration and the 90 day submission at the same time will facilitate the agency's review.

3. New Infant Formula Submission

Section 412(c)(1)(B) of the act requires that manufacturers of a new infant formula submit to FDA a notice of their intent to market the new formula that complies with section 412(d)(1) of the act. The notice must be submitted at least 90 days before the infant formula is introduced or delivered for introduction into interstate commerce[6]. Proposed § 106.120 implements this requirement.

Proposed § 106.120(a) sets out the requirement that a manufacturer submit a notice of its intent to market a new infant formula and provides the address to which such notices are to be submitted.

Proposed § 106.120(b) sets forth the information that manufacturers must include in their new infant formula submission. This proposed regulation implements and specifies the information called for in section 412(d)(1) of the act.

a. *General information required in a 90-day submission*. Because the registration of a new infant formula (proposed § 106.110) need not accompany the new infant formula submission (proposed § 106.120), and because a third submission on a newinfant formula that verifies that the new infant formula, as produced, contains all required nutrients (see proposed § 106.130) will be submitted separately, FDA has tentatively concluded that the name of the infant formula is needed to ensure that all information on a particular infant formula is filed together and is available to determine whether the agency should object to the marketing of the formula. Information on the form of the product is necessary for an accurate evaluation of the product because different

[6] While section 412(c)(1) and (c)(1)(B) of the act state ''No person shall introduce or deliver for introduction into interstate commerce any new infant formula unless—such person has at least 90 days before marketing such new infant formula, made the submission to the Secretary required by'' section 412(c)(1) of the act, FDA has recognized since 1986 that this citation is in error (see ''Requirements for Infant Formulas'' published by FDA's Industry Programs Branch, CFSAN), and that the correct citation is section 412(d)(1). This correction agrees with the language of section 412(d)(1) of the act, which states what a submission about any infant formula subject to section 412(c) of the act should include. It is also consistent with the rules of statutory construction. See *Colonial Life & Accident Insurance Co.* v. *American Family Life Assurance Co.*, 846 F. Supp. 454, 463 n. 14(D.S.C. 1994) (where the legislature has made a mistake in reference, and its intent is manifest, the statute may be read as corrected in order to give effect to the legislative intent).

requirements may apply to different forms of a formula. For example, powdered infant formula must meet the microbiological quality requirements in proposed § 106.55, whereas liquid forms of a formula do not. Therefore, FDA is proposing to require this information in § 106.120(b)(1), under the authority of sections 412(d)(1) and 701(a) of the act, even though it is not explicitly required in section 412(d)(1).

Proposed § 106.120(b)(2) requires that the submission include an explanation of why the formula is a new infant formula to facilitate a determination by the agency as to the type of evaluation the new infant formula requires. For example, if the formula is a new infant formula because a new manufacturing plant will be used to produce it, but the formulation of the product is not changed, FDA will evaluate the processing and arrange to inspect the new facility but may conclude that testing to provide assurance that quality factor requirements have been met is not necessary. Thus, FDA is proposing to require the submission of this information, even though, like the information required under proposed § 106.120(b)(1), submission of this information is not specifically provided for in the act. The agency tentatively concludes that this information is necessary for the efficient enforcement of sections 412(c)(1)(B) and (d)(1) of the act.

b. *Formulation and processing information required in a 90-day submission.* Pursuant to section 412(d)(1)(A) of the act, proposed § 106.120(b)(3) requires that the submission include the quantitative formulation of the infant formula. The agency is proposing that, if the notice concerns more than one form of the formula, the submission include quantitative information on each form of the formula that is the subject of the notice. FDA is proposing to require that manufacturers submit the formulation in units per volume (for liquid formulas) or units per dry weight (for powdered formulas) because formulations expressed in these units will facilitate agency understanding of the formula. Manufacturers already will have the formulation available in these units as a part of the master manufacturing order, and submitting the formulations in these units should not require additional calculations by the manufacturer.

Proposed § 106.120(b)(3) also requires, under section 412(d)(1)(B) of the act, that the submission include a description of any reformulation of the infant formula, including a listing of each new or changed ingredient and a discussion of the effect of such changes on the nutrient levels in the formulation. For example, if the protein source in an infant formula is replaced with a protein source that contains a different amount of protein (e.g., from casein to a mixture of casein and whey), it is important to ensure that the amount of the new protein source used will provide the amount of protein required by § 107.100. As another example, if an ingredient such as sodium selenite is added to the formula for the first time, it is important to ensure that the level of the ingredient provides selenium (in the form of selenite) at a level that is consistent with the infant's needs and yet within the safe range of selenium intake.

Proposed § 106.120(b)(4) requires that the submission include a description, when applicable, of any change in processing of the infant formula, and that such description identify the specific change in processing, including side-by-side, detailed schematic diagrams comparing the new processing to the previous processing (including processing times and temperatures). This proposed requirement implements section 412(d)(1)(B) of the act, which states that the submission must include a description of any change in the processing of an infant formula. FDA is proposing that the description of the change in processing include detailed schematic diagrams comparing the new processing to the previous processing because schematic diagrams are efficient tools for identifying the nature and significance of changes in processing.

c. *Assurance that the infant formula will not be marketed unless it meets quality factor and nutrient requirements of the act.* Pursuant to section 412(d)(1)(C) of the act, proposed § 106.120(b)(5) requires that the submission include an assurance that the infant formula will not be marketed unless it meets the quality factor requirements of section 412(b)(1) of the act and the nutrient content requirements of section 412(i) of the act.

Proposed § 106.120(b)(5)(i) requires that the assurance that the formula meets the quality factor requirements, which are set forth in subpart E of part 106, be provided by a submission that complies with § 106.121. Section 412(d)(1)(C) of the act requires that, 90 days before marketing a new infant formula, a manufacturer submit assurances that the infant formula will not be marketed unless it meets the quality factor requirements established by regulations under section 412(b)(1). Section 412(d)(2) of the act requires that, after the first production of a new infant formula and before introduction into interstate commerce of such formula, the manufacturer submit a written verification that summarizes test results and records demonstrating that such formula complies with the quality factor requirements. However, FDA has tentatively concluded that to implement sections 412 (d)(1) and (d)(2) of the act in a way that ensures that the statutory goals are achieved—that is, to ensure that the agency has all the relevant information for a sufficient period of time to conduct a meaningful review of the nutritional adequacy of the formula while enabling the infant formula manufacturer to market its product as expeditiously as possible—it is appropriate to require that the assurances that the quality factors will be met be provided by means of data that would otherwise be required as part of the verification submission. FDA notes that such a requirement would only codify current practice. Since passage of the 1986 amendments, infant formula manufacturers have been providing data demonstrating that a new infant formula meets the quality factor requirements as a part of the submission made 90 days before marketing.

Proposed § 106.120(b)(5)(ii) requires that the assurance that the formula complies with the nutrient content requirements, which are set forth in § 107.100, be provided by a statement assuring that the formula will not be marketed unless it meets the nutrient requirements of § 107.100, as demonstrated by testing required under subpart C of part 106.

The agency acknowledges that there is an apparent inconsistency in how it interprets the word ''assurance'' in section 412(d)(1)(C) of the act as it relates to assurance that the infant formula meets the quality factor requirements and assurance that the infant formula meets nutrient content requirements. FDA has tentatively concluded, however, that assurance that the formula will meet the quality factor requirements is a threshold question that must be answered affirmatively before the effort in setting up the line for first production of the infant formula would be justified. Therefore, the agency is proposing to require that the assurance that the infant formula will meet the quality factor requirements be provided by data submitted 90 days before marketing the formula.

On the other hand, the agency is proposing that the assurance that the formula will not be marketed unless it meets the nutrient requirements of § 107.100 can be provided by a statement to that effect (as opposed to data) submitted 90 days before marketing of the formula because the

data and records demonstrating that the formula complies with the nutrient requirements of § 107.100 will not be available until the production line is set up, and the first production of the infant formula has occurred. FDA will receive verification that the formula meets the nutrient requirements as a part of the submission required by section 412(d)(2) of the act (see proposed § 106.130(b)(3), below). Therefore, FDA has tentatively concluded that it is adequate to receive a commitment from the manufacturer, 90 days before marketing, that the infant formula will not be marketed unless it meets the nutrient requirements of § 107.100.

d. *Assurance that the processing of the infant formula complies with the CGMP and quality control procedures of the act.* Under section 412(d)(1)(D) of the act, proposed § 106.120(b)(6) requires that the submission include assurance that the processing of the infant formula complies with section 412(b)(2) of the act (CGMP, including quality control procedures).

Proposed § 106.120(b)(6)(i) requires that the assurance that the processing of the infant formula complies with section 412(b)(2) of the act include a statement that the formula will be produced in accordance with subparts B and C of part 106. This proposed requirement is a necessary element of the assurance required by section 412(d)(1)(D) of the act because the requirements for CGMP are set forth in subpart B and the requirements for quality control procedures are set forth in subpart C. In the Congressional Record (Ref. 1), Senator Metzenbaum stated that the amendments to the Infant Formula Act set up requirements ''which will prevent our Nation's Children from ever again being threatened by defective baby formula. The most important provision of this amendment is the simple requirement that each batch of formula must be tested for each essential nutrient that must be contained in the formula'' (Ref. 1).

Proposed § 106.120(b)(6)(ii) requires that the assurance that the processing of the infant formula complies with section 412(b)(2) of the act include the basis on which the manufacturer has concluded that each ingredient meets the requirement of proposed § 106.40(a), i.e., that the ingredient is an approved food additive, is authorized by a prior sanction issued by the agency, or is GRAS for its intended use. The statute provides that the manufacturer submit, 90 days before marketing a new infant formula, assurance that the processing of the formula complies with the CGMP regulations, and that the formula is manufactured in a way that is designed to prevent its adulteration. FDA has tentatively concluded that, to implement the act in a way that will ensure that the statutory goals are achieved, that is, to ensure that the agency has all the relevant information for a sufficient period of time to conduct a meaningful review of the formula while enabling the manufacturer to market its product as expeditiously as possible, it is appropriate to require that the assurance that none of the ingredients will adulterate the formula be provided by an explanation of how each ingredient meets proposed § 106.40(a). FDA has tentatively concluded that this approach is appropriate because, like the evidence that the formula meets the quality factors, evidence that all the ingredients in the infant formula are safe goes to a threshold question that must be answered affirmatively before the effort in setting up the production line for the first production of the infant formula would be justified. Moreover, an infant formula manufacturer would want to have information demonstrating that each of the ingredients in the formula is safe before marketing the formula, because without such information, a responsible manufacturer would not include the ingredient in its product.

FDA will review the new infant formula submission to ensure that a safe product will be produced (sections 201(s), 402(a)(1) and (a)(2), and 409 of the act). If the agency is not presented with basis on which it can be satisfied that the use of an ingredient in an infant formula will be safe, FDA will not be able to acquiesce in the marketing of the formula. The legislative history of the 1986 amendments supports that Congress anticipated that FDA would provide this type of review. In the Congressional Record of September 27, 1986, Senator Metzenbaum stated:

> I continue to be concerned, however, that our food and drug laws do not differentiate between foods and infant formulas. But they are fundamentally different. An infant formula is designed as the sole source of nutrition for a baby. An infant formula is used daily. A baby must thrive from its content for the first and most formative months of his or her life. I expect the Secretary to look closely at whether or not our standards in this area for foods are adequate standards for infant formula. I have no reason at this time to suspect that there is a problem here. But I continue to urge the Secretary to give thorough consideration to the important distinctions between infant formula and other foods, as well as food additives which may be used with infant formulas. (Ref. 1)

One way for a manufacturer to satisfy the agency that proposed § 106.40(a) is met would be for the manufacturer to use only ingredients that are: (1) Listed as GRAS for such use in 21 CFR part 182 or affirmed as GRAS for such use in 21 CFR part 184 or otherwise GRAS for such use under the regulations included in those parts; (2) approved for such use by a food additive regulation; or (3) authorized by a prior sanction issued by FDA.

Alternatively, the requirements of proposed § 106.40(a) can be met by a showing that the substance is GRAS within the meaning of § 170.30 (21 CFR 170.30), which states that ''general recognition of safety may be based only on the view of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to foods'' (§ 170.30(a)). To clarify this point, § 170.30(a) states that ''[g]eneral recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.'' The qualified experts can base their views on either: (1) Scientific procedures, or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food (section 201(s) of the act).

Under § 170.30(b), general recognition of safety based upon scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of the ingredient as a food additive, and it must ordinarily be based on published studies, which may be corroborated by unpublished studies and other data and information. If the manufacturer of an infant formula wishes to use an ingredient because there is general recognition of safety based upon scientific procedures, FDA is proposing to require in § 106.120(b)(6)(ii) that the manufacturer include as a part of its new infant formula 90-day submission the rationale for why the ingredient is GRAS and the evidence that demonstrates that there is common knowledge about the safety of the substance throughout the scientific community knowledgeable about the safety of such substance. FDA is proposing that this evidence include a bibliography of published studies, copies of those scientific publications about the substance, and an explanation as to why, based on the published studies, the use of the substance in infant formula is GRAS.

Under § 170.30(c)(1), if a substance is GRAS based on common use in food prior to January 1, 1958, this determination must be based solely on

food use of the substance before January 1, 1958, and must ordinarily be based upon generally available data and information. Thus, GRAS based on common use in food prior to January 1, 1958, may be determined without the quantity or quality of scientific procedures required for approval of a food additive regulation. If the manufacturer of an infant formula wishes to use an ingredient based solely on food use of the substance prior to January 1, 1958, it should provide as a part of the new infant formula 90-day submission the evidence supporting that the ingredient was in common use in infant formula prior to January 1, 1958, and an explanation of why that use provides the basis for general recognition of the safety of the substance.

FDA has recognized that it is impractical to list all substances that are GRAS for their intended use based on their common use in food prior to 1958 (see 21 CFR 182.1(a)). The agency regards such common food ingredients as salt, pepper, vinegar, and baking powder as safe for their intended use. Also, current § 170.30(d) provides that a ''food ingredient of natural biological origin that has been widely consumed for its nutrient properties in the United States prior to January 1, 1958, without known detrimental effects, which is subject only to conventional processing as practiced prior to January 1, 1958, and for which no known safety hazard exists, will ordinarily be regarded as GRAS * * *.'' Some ingredients are used in infant formulas even though they are not listed or affirmed as GRAS by the agency for their intended use. Vitamin K, for example, is required to be a part of an infant formula under section 412(i) of the act and, in the form of phylloquinone, is considered to be safe and suitable for infant formulas when used in accordance with prescribed levels in § 107.100, although no source of vitamin K, such as phytonadione or phylloquinone, has been listed or affirmed as GRAS by the agency. Likewise, sodium selenite has been added to infant formulas to provide the amount of selenium that has been determined to be essential for infants by NAS (Ref. 19). Published experimental and clinical data provide a basis upon which experts qualified by scientific training and experience could evaluate the safety of sodium selenite as a source of selenium for use in infant formula and could conclude that it is safe. The agency anticipates that other ingredients may be shown to be GRAS because they are generally accepted sources of substances that are established as essential for infants by an authoritative body such as NAS. However, manufacturers should not take this acknowledgment to mean that they are free to declare that the use of any ingredient they want to use is GRAS. Any ingredient that cannot meet the standard of § 170.30 for a GRAS determination will be viewed by the agency as a food additive, and any infant formula that contains a food additive that the agency has not approved for use in infant formula is subject to being acted against by the agency.

If the safety of an ingredient is not expressly recognized in an FDA regulation, the burden will rest on the manufacturer of the infant formula to include in its new infant formula submission an explanation of why the substance is GRAS under § 170.30, along with the published and other information that provides the basis for that explanation, in accordance with proposed § 106.120(b)(6)(ii). If the agency adopts this approach, a failure of the agency to object to a manufacturer's determination that an ingredient is GRAS in a new infant formula submission will not constitute a GRAS affirmation by the agency. However, if FDA knows of no reason to question the safety of an ingredient to be used in infant formula, the agency will not object to the manufacturer's relying on its own determination that use of the substance is GRAS.

e. *Submission 90 days before marketing a new infant formula intended only for export.* When a new infant formula is intended only for export, proposed § 106.120(c) provides that manufacturers may submit, in lieu of the information required under proposed § 106.120(b), a statement that the infant formula meets the specifications of the foreign purchaser, does not conflict with the laws of the country to which it is to be exported, is labeled on the outside of the shipping package to indicate that it is intended for export only, and will not be sold or offered for sale in domestic commerce. This proposed requirement recognizes that under section 801(e) of the act, in certain limited circumstances, manufacturers may lawfully export products that are adulterated or misbranded. The information required under proposed § 106.120(c) will demonstrate that those limited circumstances exist. FDA has tentatively concluded that proposed § 106.120(c) will provide manufacturers with the flexibility allowed under section 801(e) of the act while meeting the requirements of sections 412(c) and (d) of the act.

f. *Submission 90 days before marketing—administrative procedures.* Proposed § 106.120(d) states that the submission will not constitute notice under section 412 of the act unless it complies fully with § 106.120(b), and the information that it contains is set forth in a manner that is readily understandable, so that FDA can complete its review in a timely manner and advise the manufacturer if it has any concerns about the marketing of the formula before the 90 days is up. Proposed § 106.120(d) makes clear that the agency will notify the submitter if the notice is not adequate because it does not meet the requirements of sections 412(c) and (d) of the act.

Proposed § 106.120(e) provides that if a new infant formula submission contains all the information required by proposed § 106.120(b), FDA will acknowledge its receipt and notify the manufacturer of the date of receipt, which will be the filing date for the submission (and the manufacturer will be able to plan those actions necessary to begin marketing the new formula in reliance on that date). Further, pursuant to section 412(c)(1)(B) of the act, proposed § 106.120(e) also requires that the manufacturer not market the new infant formula until 90 days after the filing date. Congress provided for 90-day notice so that the agency would have sufficient time to examine all of the material submitted and decide whether there is any basis for concern about the marketing of the formula.

Proposed § 106.120(f) makes clear that if the manufacturer provides additional information in support of a new infant formula submission, FDA will determine whether it represents a substantive amendment to the submission, and that, if it does, FDA will assign the new infant formula submission a new filing date. FDA is proposing to adopt § 106.120(f) to clarify how it will treat amendments to infant formula notifications. In the 9 years since the passage of the 1986 amendments, the treatment of additional submissions has been the source of some confusion. FDA has tentatively concluded that it is necessary to give a new filing date to a new infant formula submission when a substantive amendment is made to it so that the agency has time to examine all of the material submitted and to determine whether there is any basis for concern about the marketing of the formula.

4. Quality Factor Submission

Proposed § 106.121 sets forth the requirements for specific information that a manufacturer must submit to

FDA, in accordance with proposed § 106.120(b)(5), to provide assurance that the infant formula meets the quality factor requirements set forth in subpart E of part 106. FDA has tentatively concluded that agency access to study records and data are necessary so that it can ensure that study results are meaningfully interpretable, and that the manufacturer's conclusion that the infant formula meets the quality factor requirements withstands scientific scrutiny and evaluation. Failure to adequately document study results and interpretation raises questions as to the validity of conclusions and could mean that infants have been unnecessarily subjected to testing procedures.

Proposed § 106.121(a) requires that the manufacturer submit an explanation, in narrative form, setting forth its conclusions on how all quality factor requirements of subpart E of part 106 have been met. This narrative will facilitate the agency's review by summarizing the results, and their interpretation, that provide the basis on which the manufacturer has concluded that the quality factor requirements have been met, or that the subject infant formula is eligible for the exemptions described in proposed § 106.97(a)(2) and (b)(2).

Proposed § 106.121(b) requires that the manufacturer submit records that contain the information collected during the study for each infant enrolled in the study. The measurements and information collected for each infant enrolled in the study are necessary to an evaluation of whether the infant formula supported healthy growth. Proper identification of the records is necessary for proper use and analysis of the records.

Proposed § 106.121(c)(1) requires that the manufacturer submit a statistical evaluation of the data from the clinical study, including group means, group standard deviations, and measures of statistical significance for all measurements for each feeding group at the beginning of the study and at every point where measurements were made throughout the study. This evaluation forms the basis for the manufacturer's conclusion as to whether the formula meets the quality factor requirements. Without knowledge of the statistical basis upon which the manufacturer drew its conclusions, FDA would not have sufficient information to evaluate the conclusions reported by the manufacturer.

Proposed § 106.121(c)(2) requires that the manufacturer submit a calculation of the statistical power of the study at its completion. Proposed § 106.97(a)(1)(ii)(E) recommends that the power calculation used to design the study be included in the study protocol. FDA is aware that circumstances (e.g., attrition, difficulty in recruiting sufficient numbers of infants, unexpectedly high measurement error in a particular variable) may unintentionally result in sample sizes and feeding group assignments that lack adequate statistical power for detecting differences between treatment and control groups, regardless of the apparent adequacy in planning for the study protocol. Reviewers must be aware of changes in the statistical power of a study so that they do not inadvertently misinterpret the absence of differences that occur between different formulas as meaning there are no differences. Failure to detect differences, if they are real, could result in erroneously concluding that a formula is safe and suitable for its intended use when, in fact, it is not. The agency is proposing to require that the manufacturer submit this calculation to FDA so that the agency can meaningfully review and interpret the data and study results contained in the submission.

Proposed § 106.121(d) requires that the manufacturer submit reports on attrition and on all occurrences of adverse events during the study.

FDA has tentatively found that information on the occurrence of adverse events is a critical element of the data that must be evaluated to determine whether a formula meets quality factor requirements and is safe and suitable for infants. Adverse events associated with the use of an infant formula, although unexpected, can be a sign or symptom of a nutritional inadequacy or of a safety problem with the infant formula, and failure to use these results could result in inadvertent release of an unsafe product. Conversely, adverse events can be unrelated to a formula product (e.g., flu), but their occurrence can affect the way in which results are interpreted and used. For example, illnesses can influence the interpretation of growth data and of the laboratory measurements collected to evaluate the infant formula.

For these reasons, FDA has tentatively concluded that complete reports, including the results of followup investigations, on the occurrence of all adverse events during the study, regardless of whether the adverse events are attributable to the use of the new infant formula or to some other illnesses, are necessary to properly evaluate the conclusions drawn from a clinical study (proposed § 106.121(d)(1)). FDA has tentatively concluded that a complete report on the occurrence of an adverse event must include identification of the infant by subject number to permit evaluation of infant growth measurements; identification of the feeding group to show whether there is a pattern of adverse events in one feeding group versus another; and a complete description of the adverse event, including comparisons of the frequency of occurrence in each feeding group and information on the health of the infants during the course of the study, including the occurrence and duration of any illness, that occurred during the trial, so that it is possible to evaluate the significance of the illness.

As discussed above, it is very important to be able to evaluate whether the adverse event is a result of a nutritional quality factor problem with the formula product. The results and evaluation of the infant's clinical status are essential to make this evaluation, and the health of the infant is also relevant to interpreting study endpoints, for example, growth data. Therefore, knowledge of the infant's health status is an essential piece of information in evaluating the circumstances surrounding an observed adverse event associated with use of a formula product. Thus, FDA has tentatively concluded that evaluations by a health care professional are necessary to provide the agency with relevant information on the circumstances surrounding the adverse event (see § 106.121(d)(2)) to assist the agency in evaluating the nutritional adequacy and safety of the formula product for supporting healthy growth in infants. In some cases, this clinical assessment may be carried out by the infant's health care provider, rather than the investigators conducting this clinical study, because some parents will contact the infant's health care provider if the infant experiences any adverse event during the course of the study. The agency expects that the study investigators will take sufficient measures to obtain all available information to enhance the likelihood of being able to meaningfully interpret the likely relationship of the adverse event to the formula product and its impact on study conclusions.

Attrition of infants from a study can result not only from adverse events and illnesses but also from a variety of reasons having no bearing on whether the new infant formula meets the quality factor requirements. For example, an infant enrolled in the study may be withdrawn from the study because the parents moved from the area. The effect of attrition on study results, however, must be evaluated in order to be able to meaningfully

interpret those results. To properly evaluate the impact of attrition on study results, FDA must have information that permits it to evaluate the likely cause of the attrition and its relationship to product use and study measurements. Therefore, the agency is proposing to require the submission of this information on attrition under § 106.121(d)(3).

Proposed § 106.121(e) requires that the manufacturer submit the results of the Protein Efficiency Ratio. This proposed submission requirement is necessary to provide assurance that the manufacturer has complied with proposed § 106.97(b) and to provide assurance that the infant formula meets the specific quality factor for protein quality.

Under proposed § 106.121(f), the manufacturer is required to submit a statement certifying that it has collected and considered all information and data on the ability of the infant formula to meet the quality factor requirements, and that it is not aware of anything that would show that the formula does not meet the quality factors. This proposed requirement is necessary to provide assurance that the manufacturer has complied with the regulations and considered all information and data of which it is aware, and that it has not made a selective submission of information that gives a false impression of the degree or extent to which a formula meets the quality factor requirements.

5. Verification Submissions

Proposed § 106.130(a) requires that manufacturers, after the first production, but before the introduction into interstate commerce, of a new infant formula, verify in a written submission that the infant formula complies with the requirements of the act and is not adulterated. This proposed requirement implements section 412(d)(2) of the act, which requires the submission of a written verification that summarizes test results and records demonstrating that a formula meets the requirements of section 412(b)(1), (b)(2)(A), (b)(2)(B)(i), (b)(2)(B)(iii), (b)(3)(A), (b)(3)(C), and (i) of the act. The failure to provide the notice required by section 412(d) of the act is a prohibited act under section 301(s) of the act.

Proposed § 106.130(b)(1) requires that the verification submission include the name of the new infant formula, the filing date for the new infant formula submission required under proposed § 106.120, and the identification number assigned by FDA to the new infant formula submission, so that FDA is able to match the verification submission with the appropriate new infant formula submission.

Proposed § 106.130(b)(2) requires that the verification submission include a statement that the infant formula to be introduced into interstate commerce is the same as that which was the subject of the new infant formula submission and for which the manufacturer provided assurances in accordance with the requirements of proposed § 106.120. FDA has tentatively concluded that if this statement can be made by the manufacturer, it means that the assurances that the manufacturer provided in the new infant formula submission with respect to the quality factor requirements and the safety of the ingredients remain relevant and applicable to the product. Thus, no additional information need be included in the verification to demonstrate compliance, in accordance with section 412(d)(2) of the act, with section 412(b)(1) or with this aspect of section 412(b)(2)(A).

Proposed § 106.130(b)(3) requires a summary of test results that show the levels of each nutrient required by § 107.100 in the formula and of any nutrient added by the manufacturer. This proposed requirement is necessary to demonstrate compliance with section 412(i) of the act. Section 412(i) of the act sets forth those nutrients that an infant formula must contain in order not to be adulterated, and the submission of a summary of test results as required by section 412(d)(2), and implemented by § 106.130(b)(3), is necessary to show that an infant formula, after the first production, contains all of the required nutrients at the required levels.

FDA has tentatively concluded that it is not necessary to require that the verification submission summarize test results or records demonstrating compliance with sections 412(b)(2)(A) and (b)(2)(B)(iii) of the act because the underlying records will be available for inspection by FDA. FDA has tentatively concluded that to require the manufacturer to create a report based on these records would be to require an unnecessary expenditure of effort. However, the agency is proposing to require (under § 106.130(b)(4)) that the manufacturer certify as a part of its verification submission that it has established procedures that comply with sections 412(b)(2)(A) and (b)(2)(B)(iii) of the act.

FDA has tentatively concluded that requiring additional test results or records demonstrating compliance with section 412(b)(2)(B)(i), (b)(3)(A), and (b)(3)(C) of the act would be unnecessary because such showings would be subsumed in the testing to show whether the formula meets the requirements of § 107.100 (under § 106.130(b)(3)).

Proposed § 106.130(c) makes clear the consequences of failing to comply with § 106.130 and that in such circumstances, the agency will notify the submitter that the notice is not adequate, and that the manufacturer has not met the requirements of section 412(d)(2) of the act.

6. Submissions Concerning a Change in Infant Formula That May Adulterate the Product

Proposed § 106.140(a) provides that, when a manufacturer makes a change in the formulation or processing of the formula that may affect whether the formula is adulterated under section 412(a) of the act, it shall make a submission to FDA before the first processing of such formula. This proposed requirement implements section 412(d)(3) of the act, which requires that manufacturers make the submission to FDA required by section 412(d)(1) of the act before first processing when they determine that a change in formulation or in the processing of an infant formula may affect whether the formula is adulterated under section 412(a) of the act. Examples of changes that may affect whether a formula is adulterated under section 412(a) of the act include, but are not limited to:

(1) A change in the level of an ingredient that does not constitute a major change but that may affect whether the formula meets the requirements of section 412(i) of the act (for example, decreasing the amount of an ingredient such as sodium chloride could affect whether the formula provides two nutrients required by § 107.100);

(2) A change in an ingredient in an infant formula that does not constitute a major change but that may affect whether the formula meets the quality factor requirements of subpart E of part 106 (for example, a change in the level of an emulsifier could result in a change in the bioavailability of fat because the emulsifier may interfere with fat digestion); or

(3) A change in the processing of the infant formula that does not constitute a major change but that may affect whether the CGMP requirements or the quality control procedures of subparts B and C of part 106 are met (for example, a change in the processing of the infant formula may affect whether a specification or a standard for a particular point in the manufacturing process where control is deemed

necessary to prevent adulteration is met; a change in a processing temperature or holding time may allow microorganisms to develop in violation of § 106.55; or a change in a processing temperature may affect the level of a labile (temperature sensitive) nutrient in the formula).

Proposed § 106.140(b)(1) requires that the submission include information on the name and physical form of the product, so that the change in the formula can be evaluated with other information that the agency has received on the formula, and so that an accurate evaluation of the product can be made because different requirements may apply to different forms of a formula.

Proposed § 106.140(b)(2) requires an explanation of why the change in formulation or processing may affect whether the formula is adulterated, so that the agency can determine what type of evaluation the submission requires. For example, if a change in formulation may affect nutrient levels, the agency needs to evaluate the nutrient content of the formula to be assured that this formulation change will not lead to production of a formula that will not provide a required nutrient at the required amount. Likewise, if a change in processing may affect whether the formula is adulterated, the agency will need to evaluate the formula's processing to be assured that the processing of the formula will still comply with the CGMP regulations in subpart B of part 106.

Proposed § 106.140(b)(3) requires that the submission comply with § 106.120(b)(3), (b)(4), (b)(5), and (b)(6). This proposed requirement implements section 412(d)(3) of the act, which provides that manufacturers make the submission required by section 412(d)(1). FDA has tentatively concluded that requiring that the submission comply with these aspects of § 106.120(b) will promote consistency in the form and substance of the information that industry must submit, and FDA must review. If the information required on processing by § 106.120(b)(4) has already been provided in compliance with § 106.140(b)(2) as a part of the explanation of why the change in processing may affect whether the formula is adulterated, the same information does not need to be repeated in the submission. To avoid redundant submissions, proposed § 106.140(b)(3) further provides that if the information required by § 106.120(b)(3), (b)(4), (b)(5), or (b)(6) has been provided to the agency previously, and that information is not affected by the change that is the subject of the submission, a statement to that effect, together with the identification number assigned by the agency to the relevant infant formula submission, can be provided in lieu of a new submission.

Proposed § 106.140(b)(3) requires inclusion of the identification number assigned by the agency to the infant formula submission so that the agency can have ready access to the relevant information that was previously submitted. For example, if the manufacturer makes a submission as a result of a change in processing, but the formulation will remain the same, the manufacturer need not provide the information required by § 106.120(b)(3). Likewise, if the manufacturer makes a submission as a result of a change in formulation, but the processing of the formula remains the same, the manufacturer need not submit the information required by § 106.120(b)(4).

A determination of whether the assurances required by § 106.120(b)(5) and (b)(6) need to be given is based on the manufacturer's reason for providing the submission. For example, if the submission is provided because a change in formulation or processing may affect whether the formula is adulterated because it does not meet the quality factors set forth in subpart E of part 106, the assurance required by § 106.120(b)(5)(i) would have to be provided. Likewise, if the submission is provided because a change in formulation or processing may affect whether the formula is adulterated because it does not meet the nutrient requirements of § 107.100, the assurance required by § 106.120(b)(5)(ii) would have to be provided. Further, if the submission is provided because a change in processing may affect whether the formula is adulterated because the processing of such formula may no longer be in compliance with CGMP or with appropriate quality control, as set forth in subparts B and C of part 106, or whether the formula is manufactured in a manner designed to prevent adulteration, the assurance required by § 106.120(b)(6) would have to be provided.

In proposed § 106.140(c), the agency sets forth requirements necessary to ensure that the data and other information provided in the submission are in a form that will allow FDA to complete its review in a timely manner and to advise the manufacturer if the agency has any concerns about the marketing of the formula. Proposed § 106.140(c) also makes clear that the agency will notify the submitter if the notice is not adequate because it does not meet the requirements of section 412(d)(3) of the act.

7. Notification of an Adulterated or Misbranded Infant Formula

If FDA adopts the other regulations that it has proposed, it will redesignate current §§ 107.240(a) and (b) as § 106.150 so that all notification requirements on infant formulas can be found in one place in the agency's regulations. In § 106.150(b), FDA has revised the address to reflect the reorganization of CFSAN.

H. Conforming and Editorial Changes to Part 107—Infant Formula

The agency is making conforming and editorial changes to part 107 to reflect the changes made by the 1986 amendments and the regulations that FDA is proposing to adopt in part 106. The references in part 107 to the Division of Regulatory Guidance are being changed to the Division of Enforcement to reflect the reorganization of CFSAN in November 1992.

1. Changes in Subpart A

The agency is proposing to add a new § 107.1 which will parallel proposed § 106.1. Proposed § 107.1 describes the authority for each of the proposed subparts and the consequences under the act of failure to comply with any of the regulations in the proposed subparts.

2. Changes in Subpart B of Part 107—Labeling

The agency is proposing to amend § 107.10 to require a statement of the amount, supplied by 100 kcal, of each of any nutrient added by the manufacturer as well as of the listed nutrients. As discussed previously in the quality control section of this document, infant formula manufacturers are adding ingredients to infant formula to provide nutrients, such as selenium, that are not required by § 107.100 to be in infant formulas. The proposed change to § 107.10 requires that the amount of the added nutrients supplied by 100 kcal of the formula be declared on the label of the infant formula. This proposed requirement is necessary to inform the consumer on a consistent basis of the level of all nutrients included in an infant formula.

3. Subpart C of Part 107—Exempt Infant Formulas

At this time the agency is not proposing to revise the regulations in § 107.50 pertaining to infant formulas that are subject to section 412(h) of the act. These regulations were finalized in 1985 (50 FR 48183), before passage of the 1986 amendments. In the near future, the agency intends to reevaluate

the exempt infant formula regulations and the effect of the 1986 amendments on exempt infant formulas and to issue a proposed rule to reflect the results of this reevaluation. The agency also plans to evaluate the effect of the Nutrition Labeling and Education Act of 1990 (Pub. L. 101–535) (the 1990 amendments) on the regulations for exempt infant formulas. Exempt infant formulas are specifically exempted from requirements for health claims and nutrient content claims by section 403(r)(5)(A) of the act. The basis for being an exempt infant formula, according to section 412(h)(1) of the act, is how the product is represented and labeled for use. This category of infant formula recognizes that infants who suffer from special medical disorders, such as maldigestion and malabsorption, inborn errors of metabolism such as phenylketonuria or maple syrup urine disease, or severe kidney disease, require formulas tailored specifically to their medical needs. Therefore, it is important that any claims made for these products be truthful, not misleading, and adequately substantiated because these infants make up a vulnerable population and must receive the appropriate nutrients for their medical condition. Because these formulas are exempt from the regulations governing claims that were developed under the 1990 amendments, the agency plans to evaluate how claims for these products need to be substantiated to ensure that infants with special nutritional needs are receiving appropriate infant formulas.

4. Subpart E—Infant Formula Recalls

Current § 107.240(a) sets out the requirements for notification of a violative infant formula, and current § 107.240(b) sets out the method of notification. As stated above, the agency is moving the provisions of current § 107.240(a) and (b) to § 106.150, so that all of the agency's notification requirements are in one place. The agency is renumbering current § 107.240(c)(1), (c)(2), and (c)(3) as § 107.240(a), (b), and (c).

Section 107.250 gives directions on the termination of an infant formula recall. The agency is changing the reference to the Division of Regulatory Guidance to the Division of Enforcement in § 107.250 to reflect the 1992 reorganization of CFSAN.

V. Environmental Impact

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.

VI. Analysis of Impacts

FDA has examined the impacts of the 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). According to Executive Order 12866, a regulatory action is ''economically significant'' if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs. A regulation is considered ''significant'' under Executive Order 12866 if it raises novel legal or policy issues.

The Regulatory Flexibility Act requires Federal agencies to minimize the economic impact of their regulations on small businesses. FDA finds that this proposed rule is neither an economically significant nor a significant regulatory action as defined by Executive Order 12866. In compliance with the Regulatory Flexibility Act, the agency certifies that this proposed rule, if issued, will not have a significant impact on a substantial number of small businesses. Therefore, under the Regulatory Flexibility Act, no further analysis is required. The agency examined three options in determining the economic impact of this proposed regulations. A summary of the options follow:

A. Options

FDA has three primary options: (1) Adopt regulations with more stringent requirements than the proposed regulations; (2) adopt the proposed regulations; or (3) adopt regulations with less stringent requirements than the proposed regulations.

1. Option 1—Adopt Regulations More Stringent Than the Proposed Regulations

FDA believes infant formula manufacturers already comply with most of the requirements of this proposed rule. One option would be to add provisions to this proposed rule that would require activity beyond that which is currently engaged in by infant formula manufacturers or that is likely to be engaged in by manufacturers entering the infant formula industry. Potential requirements of this type include specific production and in-process control systems, specific equipment or types of personnel, and additional testing and recordkeeping.

Under this option, incumbent manufacturers would face higher production costs and would pass most of the costs on to consumers of infant formula. In addition, the startup and operating costs would increase, and thus discourage entry into the infant formula industry. The ability of new firms to enter an industry is an important element in promoting price competition and innovation. These additional requirements would reduce price competition in the infant formula industry.

The price of infant formula is probably linked to certain risky infant feeding practices. With very high infant formula prices, some consumers may increase risks to infants by improperly diluting formula with water or other substances; using inappropriate substitutes for formula or breast milk; or prematurely switching from formula to cow's milk. For example, preliminary results of an FDA study on infant formula feeding practices showed that approximately 20 percent of infants (younger than 2 months) had their formula diluted by cereal, which is cheaper than infant formula.

2. Option 2—Adopt the Proposed Regulations

There are two types of costs associated with this option: precluded future cost cutting behavior and direct compliance costs.

a. *Future cost cutting behavior.* This type of cost may arise because the proposed rule precludes cost cutting behavior by either incumbent firms or firms entering the infant formula industry. Infant formula manufacturers currently undertake a considerable amount of activity, such as infant growth studies, that is designed to ensure the safety of infant formula but is not explicitly required by either current law or regulation. In the absence of this regulation, which mandates this activity, either incumbent or future manufacturers may choose not to undertake this activity in the future. However, because of reputation effects and liability laws, these costs are likely to be low.

b. *Direct compliance costs.* (i). *CGMP.* FDA believes that infant formula manufacturers already comply with most of the proposed CGMP's. These CGMP's include those dealing with: (1) Production and in-process control systems, including the evaluation of any deviation from these procedures or from established standards or specifications; (2) controls designed to prevent adulteration of infant formula by workers, by facilities, and during packaging and labeling; (3) controls to prevent adulteration during manufacturing, including recording and justifying deviations from the master manufacturing order and evaluating deviations from processing times; (4) controls on the release and storage of finished infant formula; (5) all requirements relating to batch production and control records, and to coding; and (6) all requirements dealing with general quality control procedures, including the testing of one batch of each physical form of infant formula at least once every 3 months.

If all manufacturers already comply with these proposed CGMP's, then no compliance costs will result from them. FDA requests comments on whether all infant formula manufacturers are already in compliance with the proposed CGMP's listed above.

FDA believes that all infant formula manufacturers already comply with the proposed CGMP's dealing with controls to prevent adulteration caused by ingredients, containers, and closures. The provision that FDA may object to the use of a particular substance in an infant formula during its prenotification review of ingredients used in a formula because it believes that the substance is not safe and suitable for that use does not represent a change in the way FDA reviews infant formula ingredients. This provision recognizes the fact that manufacturers may make independent GRAS determinations about ingredients. When a manufacturer makes such a determination, that manufacturer is not necessarily required to have the relevant ingredient affirmed as GRAS by FDA. However, FDA is reserving the right to review infant formula ingredient lists and documentation concerning whether particular ingredients are safe and suitable for use in infant formula. Theoretically, this provision could lead to a reduction in the number of ingredients that are independently determined to be GRAS and a corresponding increase in the number of ingredients for which food additive petitions are required. Petitions for direct food additives can take between 1 to 6 years to complete and cost approximately $1 million per year. However, because manufacturers of infant formula generally obtain FDA concurrence on the safety and suitability of ingredients used in infant formula before making these determinations, FDA believes no additional compliance costs will be generated by this provision.

FDA also believes that infant formula manufacturers already comply with many of the other proposed CGMP's. Provisions of CGMP's that some infant formula manufacturers may not currently be in compliance include the following:

(1) Controls to prevent adulteration caused by equipment or utensils. Some manufacturers may not repair or replace instruments and controls when those instruments and controls cannot be adjusted to within essential agreement with the reference standard. In addition, most manufacturers probably do not perform a written evaluation of all affected product, or of actions taken when calibration results indicate that a specification or standard for a point where control is deemed necessary to prevent adulteration has not been met. FDA cannot estimate the repair or replacement costs of instruments and controls at this time. Written evaluations will take a supervising technician an estimated 2 hours to complete, which will generate some small compliance costs.

(2) Controls to prevent adulteration because of automatic, mechanical, and electronic equipment. Most manufacturers will probably have to perform additional analysis of software modifications. FDA preliminarily estimates this analysis will add approximately 1 month to the time required to analyze programming and software modifications. One or two software modifications are probably made each year at each of the fifteen plants that produce infant formula. Assuming that a single computer scientist works on the additional activity required, compliance costs are estimated to be about $100,000 per year.

ii. *Audits, Quality factors, registration and notification requirements, and infant formula recalls.* FDA believes that infant formula manufacturers already comply with the following provisions: (1) Regularly scheduled audits to determine compliance with CGMP's and Quality Control Procedures (QCP's), (2) growth and development studies to be submitted under certain conditions and new notification requirements (FDA already requests and receives these quality factor growth and development studies and notification material based on FDA's interpretation of the language of the 1986 amendments), and (3) all provisions involving registration and notification requirements.

If infant formula manufacturers are already complying with these provisions, then no compliance costs will be generated by these provisions.

FDA requests information on whether all infant formula manufacturers already comply with all provisions listed above, particularly those provisions dealing with quality factors.

iii. *Records.* Under the current proposal, the records produced and maintained by infant formula manufacturers to establish compliance with FDA regulations will have to be expanded to include all new CGMP's and QCP's. FDA believes most of the specified records are already being kept by all firms; however, some records may not be. A plausible assumption is that current annual industry expenditures on recordkeeping may increase by about 10 percent, or $450,000 per year based on information received from industry on current recordkeeping costs. FDA requests information on the cost of increased recordkeeping.

iv. *Administrative costs.* Interpreting and implementing changes in CGMP and QCP regulations generate administrative costs even when all activity required in those CGMP's and QCP's is already being done. FDA does not have information on the administrative costs involved in interpreting and implementing changes in CGMP and QCP regulations; however, it is plausible to suppose that 20 percent of the total compliance costs other than administrative costs may be used to reflect administrative costs.

Administrative costs under this assumption would be approximately $100,000 and would accrue in the first year only. FDA requests information on administrative costs.

3. Option 3—Adopt Regulations Less Stringent Than the Proposed Regulations

Another option is to limit the activity required by this proposed rule to activity already engaged in by all incumbent infant formula manufacturers. In this case, there would be no compliance costs based on current behavior. However, in the absence of this proposed rule, incumbent or new manufacturers might choose not to undertake all activity specified in this proposed rule. Therefore, the only costs associated with this option are the costs associated with precluded potential future behavior on the part of incumbent or new manufacturers.

B. Benefits

1. Option 1—Adopt Regulations More Stringent Than the Proposed Regulations

More stringent regulations for infant formula would cause infant formula manufacturers to undertake further activity to ensure the safety of infant formula. If there were identifiable risks from infant formula that were not addressed by this proposal, then this additional activity might decrease those health risks. However, FDA is not aware of identifiable health risks from infant formula that are not addressed by this proposal.

2. Option 2—Adopt the Proposed Regulations

The proposed regulation has two primary benefits: A potential direct reduction in the health risks posed by infant formula, and a potential reduction in the cost of entering the infant formula industry. The latter effect could lead to an increase in the competitiveness of the infant formula industry, resulting in lower infant formula prices and a reduction in the incidence of risky infant feeding practices linked to high infant formula prices.

One example of a current activity that can be linked to a direct reduction in health risks but that is not explicitly required by current law or regulation is the performance of growth studies for new infant formulas. FDA currently requests and receives these studies to demonstrate that the infant formula meets the quality factor requirements of section 412(b)(1) of the act. However, because section 412(b)(1) of the act does not list specific quality factors that infant formulas must meet, a quality factor for healthy growth currently is not expressly stipulated. In the absence of this proposed rule, manufacturers could decline to perform these growth studies in the future with a potential consequence that products that do not support normal growth would be marketed. Low growth rates would not be detected by existing regulatory and legal requirements that measure only the levels of required nutrients because the required nutrients may be present but not be bioavailable, and there is no mechanism for testing bioavailability other than the proposed studies.

An example of a formula associated with low growth rates that would not have been detected in the absence of growth studies was an experimental formula that contained a source of fatty acids not previously used in infant formula. Because only a small amount of the new fat source was added to a commercial formula, it is reasonable to assume that all required nutrients were present within legal specifications. Consequently, it would likely have met all current regulations. Nonetheless, this formula was found to result in low infant growth rates (Ref. 87). In this case, the manufacturer undertook the necessary growth studies and detected the problem on its own. However, manufacturers might not undertake these studies on their own in the future. In addition, even if manufacturers continue to undertake these studies in the absence of this regulation, they may not do these studies correctly.

In general, low rates of infant growth are associated with higher than normal levels of infant morbidity. If a problem of this type were to occur, a large number of infants could potentially be affected.

Other types of current activity can also be linked to a direct reduction in health risks and also are not explicitly required by current law or regulation. In the absence of this regulation, incumbent or new manufacturers may not undertake this activity in the future. However, as explained earlier, because of reputation effects and legal liability, such a refusal seems unlikely.

An example of a health risk from infant formula is the 1978 incident, discussed elsewhere in this document, in which a required nutrient was missing from an infant formula. Recurrence of this particular problem is unlikely because section 412(d)(1)(A) of the act already explicitly requires the submission of the quantitative formulation of an infant formula as part of the mandatory FDA notification of a new infant formula. Recurrence of this problem is also made unlikely because section 412(b)(2) of the act already explicitly requires the testing of infant formula for all required nutrients. However, the risk of a formula being sold without a required nutrient is minimized to the extent possible by specifically clarifying this part of the infant formula law in the regulation.

Another example of a health risk associated with infant formula is an incident in which infant formula was found to contain *Salmonella.* It appears that the manufacturer was testing for *Salmonella* in a manner consistent with the testing requirements of this proposed rule, and therefore it is not clear that this particular incident would have been avoided if the proposed rule had been in effect. This proposed rule will reduce the risk of microbiological contamination, however, because it requires manufactures to institute a production and in-process control system. The production and in-process control system establishes standards or specifications to be met throughout the production of their product. Other provisions of the proposed regulation that will also help to prevent microbiological contamination of infant formulas are controls to prevent adulteration by workers (proposed § 106.10), controls on the required temperature of cold storage compartments used for storing ingredients and uncanned infant formula (proposed § 106.30(e)(2)), controls on the monitoring of the temperature of both cold storage and thermal processing equipment (proposed § 106.30(e)), controls on the spray-drying process for powdered infant formula including the filtering of the intake air before heating to prevent microbial growth (proposed § 106.50(d)(2)), and controls to ensure that each container of finished product is properly sealed (proposed § 106.50(d)(4)).

The incident in which infant formula was found to contain *Salmonella* resulted in two reported cases of salmonellosis in infants. The average value of preventing a single case of salmonellosis is estimated to be about $2,000 (Ref. 88). If an incident like this is avoided in the future because of this proposed rule, the value of the adverse health effects avoided would be a benefit of this proposed rule.

This incident also resulted in two recalls. FDA estimates a combined cost, including costs that accrued to both the manufacturer and FDA of approximately $0.7 million per recall. If an incident like this is avoided in the future because of this proposed rule, the recall costs that would otherwise have been associated with this incident would also be a benefit of this proposed rule.

Another benefit of the proposed regulations is a potential reduction in the administrative and time costs of entering the infant formula industry. Currently, infant formula manufacturers must analyze and interpret the relevant laws to determine the legal requirements involved in the manufacture of infant formula. Incumbent firms have tended to accept FDA's interpretations of these laws and have received information on this interpretation incrementally over time, chiefly through direct contact with FDA on various issues.

It is reasonable to expect that potential entrants into the infant formula industry would also prefer to rely on FDA's interpretations of the relevant laws. However, considerable time and administrative costs are involved in obtaining this information because there is no established

mechanism by which manufacturers can obtain this information other than direct communication with FDA on various particular issues. By providing an explicit specification of the activities that are required by the relevant laws, the proposed regulations, if adopted, will reduce the time and administrative costs involved in entering this industry.

In order to determine the net effect of the proposed rule on the cost of entering the infant formula industry, the reduction in time and administrative costs must be weighed against the additional compliance costs imposed by this proposed rule on new firms. These countervailing compliance costs are probably low because new firms will probably undertake voluntarily the same activity that is currently undertaken voluntarily by incumbent manufacturers. Therefore, the net effect of this proposed rule is likely to be the reduction in the cost of entering the infant formula industry. Publication of the proposed and final regulations will provide a means of expedited entry for new firms into the infant formula market.

A reduction in the cost of entering the infant formula industry will promote both price competition and innovation in this industry. Increased price competition may lead to health benefits because, as stated above, high infant formula prices may encourage some consumers to: (1) Improperly dilute infant formula to reduce the cost per serving; (2) prematurely switch from infant formula to cow's milk; or (3) use inappropriate substitutes for breast milk and infant formula.

A final benefit of this proposed rule is the cost savings generated by the elimination of the current FDA requirement that a vitamin D rat bioassay be performed for all major changes in infant formula. In 1992, there were approximately 50 major changes. The cost of a rat bioassay for vitamin D for infant formula at a private lab is about $1,070 (Ref. 89). Infant formula manufacturers should therefore save approximately $54,000 in testing costs per year.

3. Option 3—Adopt Regulations Less Stringent than the Proposed Regulations

Except for the value of the risk reductions resulting from requirements that go beyond activity currently undertaken by infant formula manufacturers the benefits of this option are identical to those of Option 2.

C. Conclusions

In accordance with Executive Order 12286, FDA has analyzed the economic effects of this proposed rule and has determined that this rule, if issued, will not be a significant rule as defined by that order. In accordance with the Regulatory Flexibility Act, FDA certifies that the proposed rule will not have a significant impact on a substantial number of small businesses.

The primary compliance costs of Option 2 include both direct costs of new requirements and precluded production cost reductions which may occur without this regulation. FDA has estimated direct costs to incumbent manufacturers to be approximately $0.7 million in the first year and $0.6 million each additional year. An additional cost to incumbent manufacturers is the cost of repairing or replacing instruments and controls when those instruments and controls cannot be adjusted to agreement with the reference standard. FDA has insufficient information to estimate this cost. FDA does not expect compliance with the proposed regulations to cause any significant increase in the price of infant formula products. However, the agency requests comments about any potential effects of the proposed regulations on the price of infant formula products.

The primary benefit of Option 2 is the reduction in the risk that defective infant formula will be produced, go undetected, and reach the market. FDA has insufficient information to estimate this potential benefit. In addition, this proposed rule is also expected to reduce the time and administrative costs of entering the infant formula industry. This benefit may increase price competition in the infant formula industry and reduce the health risks associated with high infant formula prices. FDA also has insufficient information to estimate these benefits.

Except for the costs and benefits associated with activity required by this proposed rule that some incumbent manufacturers do not currently undertake, the costs and benefits of Option 3 are identical to those of Option 2. FDA has insufficient information to estimate either the costs or benefits of this option.

Option 1 is expected to have higher costs and lower benefits than either Option 2 or Option 3.

VII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description for the proposed collection of information are shown below, along with an estimate of the annual recordkeeping and periodic reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary information, and completing and submitting the registrations, notifications, and other submissions that would be required under the proposed regulations.

FDA solicits public comment in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques, where appropriate or other forms of information technology.

Title: Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for the Production of Infant Formula.

Description: FDA is proposing regulations on recordkeeping requirements that include: (1) Records pertaining to batch production and control; (2) records pertaining to current good manufacturing practice and quality control; (3) records pertaining to distribution of the infant formula; and (4) records pertaining to regularly scheduled audits. FDA is also proposing regulations on reporting requirements pertaining to: (1) Registration of a new infant formula; (2) submission requirements for a new infant formula; (3) submission requirements to provide assurance that an infant formula meets the quality factor requirements; (4) submission requirements when there is a change in the formulation or processing of the formula that may affect whether the formula is adulterated; and (5) submission requirements to provide assurance that the infant formula complies with the requirements of the Federal Food, Drug, and Cosmetic Act and is not adulterated.

Description of Respondents: Infant Formula Manufacturers.

ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR	No. of recordkeepers	Annual frequency of recordkeeping	Total annual records	Hours per recordkeeping	Total hours
106.6	5	1	5	200	1,000
106.20(f)(4) and 106.100(f)(1)	5	52	260	3	780
106.30(d) and 106.100(f)(2)	5	25	125	4	500
106.30(e)(3)(ii) and 106.100(f)(3)	5	365	1,825	2	3,650
106.30(f) and 106.100(f)(4)	5	365	1,825	3	5,475
106.35(c) and 106.100(f)(5)	5	2	10	500	5,000
106.40(d)	5	20	100	30	3,000
106.40(g) and 106.100(f)(6)	5	122	610	4	2,440
106.50	5	1	5	200	1,000
106.55(d) 106.100(e)(5)(ii), and 106.100(f)(7)	5	182	910	3	2,730
106.60(c)	5	1	5	40	200
106.91(c), 106.100(e)(5)(i), and 106.100(f)(7)	5	365	1,825	4	7,300
106.94	5	1	5	88	440
106.97	5	0.6	3	225	675
106.100(e)	5	365	1,825	9	16,425
Total					50,615

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR	No of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
106.110	3	NA	20	1	20
106.120	3	NA	20	49	980
106.121	3	NA	10	50	500
106.130	3	NA	20	2	40
106.140	3	NA	25	5–10	125–250
Total					1,790
Total Recordkeeping and Reporting Burden	52,405				

FDA tentatively concludes that there are no capital costs or operating and maintenance costs associated with the reporting and recordkeeping provisions of this proposed rule. However, the agency welcomes comments on any such anticipated costs.

As required by section 3507(d) of the Paperwork Reduction Act of 1995, FDA has submitted a copy of this proposed rule to OMB for its review of the information collection requirements. Other organizations and individuals interested in submitting comments regarding this burden estimate or any aspect of these information collection requirements, including suggestions for reducing the burden, should direct them to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, ATTN: Desk Officer for FDA. Written comments on the information collection should be submitted by August 8, 1996.

VIII. Requests for Comments

Interested persons may, on or before October 7, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects

21 CFR Part 106

Food grades and standards, Infants and children, Nutrition, Reporting and recordkeeping requirements, Incorporation by reference.

21 CFR Part 107

Food labeling, Infants and children, Nutrition, Reporting and recordkeeping requirements, Signs and symbols.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to Commissioner of Food and Drugs, it is proposed that 21 CFR parts 106 and 107 be amended as follows:

PART 106—INFANT FORMULA—REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS

1. The authority citation for 21 CFR part 106 continues to read as follows:

Authority: Secs. 201, 412, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 350a, 371).

2. The heading for part 106 is revised to read as set forth above.

3. Section 106.1 is revised to read as follows:

§ 106.1 Status and applicability of the regulations in part 106.

(a) The criteria set forth in subparts B, C, and D of this part prescribe the steps that manufacturers must take under section 412(b)(2) and (b)(3) of the Federal Food, Drug, and Cosmetic Act (the act) in processing infant formula. If the processing of the formula does not comply with any regulation in subparts B, C, or D of this part, the formula will be deemed to be adulterated under section 412(a)(3) of the act.

(b) The criteria set forth in subpart E of this part prescribe the quality factor requirements that infant formula must

meet under section 412(b)(1) of the act. If the formula fails to comply with any regulation in subpart E of this part, it will be deemed to be adulterated under section 412(a)(2) of the act.

(c) The criteria set forth in subpart F of this part implement the record retention requirements established in section 412(b)(4) of the act. Failure to comply with any regulation in subpart F of this part is a violation of section 301(e) of the act.

(d) The criteria set forth in subpart G of this part describe the circumstances in which infant formula manufacturers are required to register with, submit to, or notify the Food and Drug Administration, and the content of those registrations, submissions, or notifications, under section 412(c), (d), and (e) of the act. Failure to comply with any regulation in subpart G of this part is a violation of section 301(s) of the act.

4. Section 106.3 is revised to read as follows:

§ 106.3 Definitions.

The definitions in this section and the definitions contained in section 201 of the Federal, Food, Drug, and Cosmetic Act (the act) shall apply to infant formula requirements in 21 CFR part 106 and part 107 of this chapter.

(a) *Batch* means a specific quantity of an infant formula or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

(b) *Final-product-stage* means the point in the manufacturing process, before distribution of an infant formula, at which the infant formula is homogeneous and is not subject to further degradation due to processing.

(c) *Indicator nutrient* means a nutrient whose concentration is measured during the manufacture of an infant formula to confirm complete addition and uniform distribution of a premix or other substance of which the indicator nutrient is a part.

(d) *Infant* means a person not more than 12 months of age.

(e) *Infant formula* means a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

(f) *In-process batch* means a combination of ingredients at any point in the manufacturing process before packaging.

(g) *Lot* means a batch, or a specifically identified portion of a batch, having uniform character and quality within specified limits; or, in the case of an infant formula produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures its having uniform character and quality within specified limits.

(h) *Lot number, control number, or batch number* means any distinctive combination of letters, numbers, symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of infant formula or other material can be determined.

(i) *Major change* in an infant formula means any new formulation, or any change of ingredients or processes where experience or theory would predict a possible significant adverse impact on levels of nutrients or bioavailability of nutrients, or any change that causes an infant formula to differ fundamentally in processing or in composition from any previous formulation produced by the manufacturer. Examples of infant formulas deemed to differ fundamentally in processing or in composition include:

(1) Any infant formula produced by a manufacturer who is entering the U.S. market;

(2) Any infant formula powder processed and introduced for commercial or charitable distribution by a manufacturer who previously only produced liquids (or vice versa);

(3) Any infant formula having a significant revision, addition, or substitution of a macronutrient (i.e., protein, fat, or carbohydrate), with which the manufacturer has not had previous experience;

(4) Any infant formula manufactured on a new processing line or in a new plant;

(5) Any infant formula manufactured containing a new constituent not listed in section 412(i) of the act, such as taurine or L-carnitine;

(6) Any infant formula processed by a manufacturer on new equipment that utilizes a new technology or principle (e.g., a change from terminal sterilization to aseptic processing); and

(7) An infant formula for which there has been a fundamental change in the type of packaging used (e.g., changing from metal cans to plastic pouches).

(j) *Manufacturer* means a person who prepares, reconstitutes, or otherwise changes the physical or chemical characteristics of an infant formula or packages or labels the product in a container for distribution.

(k) *Microorganisms* means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance.

(l) *New infant formula* means:

(1) An infant formula manufactured by a person that has not previously manufactured an infant formula for the U.S. market, and

(2) An infant formula manufactured by a person that has previously manufactured infant formula and in which there is a major change in processing or formulation from a current or any previous formulation produced by such manufacturer.

(m) *Nutrient* means any vitamin, mineral, or other substance or ingredient that is required in accordance with the table set out in section 412(i)(1) of the act or by regulations issued under section 412(i)(2) or that is identified as essential for infants by the Food and Nutrition Board of the National Research Council through its development of a Recommended Dietary Allowance or an Estimated Safe and Adequate Daily Dietary Intake range, or that has been identified as essential for infants by the Food and Drug Administration through a Federal Register publication.

(n) *Nutrient premix* means a combination of ingredients containing two or more nutrients received from a supplier or prepared by an infant formula manufacturer.

(o) *Quality factors* mean those factors necessary to demonstrate that the infant formula, as prepared for market, provides nutrients in a form that is bioavailable and safe as shown by evidence that demonstrates that the formula supports healthy growth when fed as a sole source of nutrition.

(p) *Representative sample* means a sample that consists of a number of units that are drawn based on rational criteria, such as random sampling, and intended to ensure that the sample accurately portrays the material being sampled.

(q) *Shall* is used to state mandatory requirements.

(r) *Should* is used to state recommended or advisory procedures or to identify recommended equipment.

5. Part 106 is amended by redesignating subparts B, C, and D as subparts C, F, and G, respectively, and adding new subparts B, D, and E; and by revising newly redesignated subparts C and G to read as follows:

* * * * *

Subpart B—Current Good Manufacturing Practice

§ 106.5 Current good manufacturing practice.

(a) The regulations set forth in this subpart and, for liquid infant formulas, in part 113 of this chapter define the minimum current good manufacturing practices that are to be used in, and the facilities or controls that are to be used for, the manufacture, processing, packing, or holding of an infant formula. Compliance with these provisions is necessary to ensure that such infant formula provides the nutrients required under § 107.100 of this chapter and is manufactured in a manner designed to prevent its adulteration.

(b) The failure to comply with any regulation set forth in this subpart or, for liquid infant formulas, in part 113 of this chapter in the manufacture, processing, packing, or holding of an infant formula shall render such infant formula adulterated under section 412(a)(3) of the Federal Food, Drug, and Cosmetic Act (the act).

§ 106.6 Production and in-process control system.

(a) Manufacturers shall conform to the requirements of this subpart by implementing a system of production and in-process controls. This production and in-process control system shall cover all stages of processing, from the receipt and acceptance of the raw materials, ingredients, and components through the storage and distribution of the finished product and shall be designed to ensure that all the requirements of this subpart are met.

(b) The production and in-process control system shall be set out in a written plan, or set of procedures, that is designed to ensure that an infant formula is manufactured in a manner that will prevent adulteration of the infant formula.

(c) At any point, step, or stage in the production process where control is necessary to prevent adulteration, the manufacturer shall:

(1) Establish standards or specifications to be met;

(2) Monitor the production and in-process control point, step, or stage;

(3) Establish corrective action plans for use when a standard or specification established in accordance with paragraph (b)(1) of this section is not met;

(4) Review the results of the monitoring required by paragraph (c)(2) of this section, and review and evaluate the public health significance of any deviations from standards or specifications that have been established in accordance with paragraph (c)(1) of this section. This review shall be conducted by an individual qualified by training and experience to conduct such reviews; and

(5) Establish recordkeeping procedures, in accordance with § 106.100(e)(3), that ensure that compliance with the requirements of this section is documented.

§ 106.10 Controls to prevent adulteration by workers.

(a) There shall be sufficient personnel, qualified by training and experience, to perform all operations, including all required recordkeeping, in the manufacture, processing, packing, and holding of each infant formula and to supervise such operations to ensure that they are correctly and fully performed.

(b) Personnel working directly with infant formula, infant formula raw materials, infant formula packaging, or infant formula equipment or utensil contact surfaces shall practice good personal hygiene to protect the infant formula against contamination. Good personal hygiene includes, but is not limited to:

(1) Wearing clean outer garments and, as necessary, protective apparel such as head, face, hands, and arm coverings; and

(2) Washing hands thoroughly in a hand washing facility with soap and running water at a suitable temperature before starting work, after each absence from the work station, and at any other time when the hands may become soiled or contaminated.

(c) Any person who reports that he or she has, or appears by medical examination or supervisory observation to have, an illness, open lesion, including boils, sores, or infected wounds, or any other source of microbial contamination that creates a reasonable possibility that the safety of an infant formula may be adversely affected, shall be excluded from direct contact with ingredients, containers, closures, in-process materials, equipment, utensils, and infant formula product until the condition is corrected or determined by competent medical personnel not to jeopardize the safety of the infant formula.

§ 106.20 Controls to prevent adulteration caused by facilities.

(a) Buildings used in the manufacture, processing, packing, or holding of infant formula shall be maintained in a clean and sanitary condition and shall have space for the separation of incompatible operations, such as the handling of raw materials, the manufacture of the product, and packaging and labeling operations.

(b) Separate areas shall be designated for holding raw materials, in-processing materials, and final product infant formula:

(1) Pending release for use in infant formula production or pending release of the final product,

(2) After rejection for use in infant formula and before disposition, and

(3) After release for use in infant formula production or after release of the final product.

(c) Lighting shall allow easy identification of raw materials,

packaging, labeling, in-process materials, and finished products that have been released for use in infant formula production and shall permit the easy reading of instruments and controls necessary in processing, packaging, and laboratory analysis. Any lighting fixtures directly over or adjacent to exposed raw materials, in-process materials, or bulk (unpackaged) finished product shall be protected to prevent glass from contaminating the product in the event of breakage.

(d) Air filtration systems, including prefilters and particulate matter air filters, shall be used on air supplies to production areas where ingredients or infant formula are directly exposed to the atmosphere.

(e) All rodenticides, insecticides, fungicides, fumigating agents, and cleaning and sanitizing agents shall be stored and used in a manner that protects against contamination of infant formula.

(f)(1) Potable water used in the manufacture of infant formula shall meet the standards prescribed in the Environmental Protection Agency's (EPA's) Primary Drinking Water Regulations set forth in 40 CFR part 141, except that the fluoride level of the water used in infant formula manufacturing shall be as low as possible. The water shall be supplied under continuous positive pressure in a plumbing system that is free of defects that could contaminate an infant formula.

(2) Manufacturers shall test representative samples of the potable water drawn at a point in the system at which the water is in the same condition that it will be when it is used in infant formula manufacturing.

(3) Manufacturers shall conduct the tests required by paragraph (f)(2) of this section with sufficient frequency to ensure that the water meets the EPA's Primary Drinking Water Regulations but shall not conduct these tests less frequently than annually for chemical contaminants, every 4 years for radiological contaminants, and weekly for bacteriological contaminants.

(4) Manufacturers shall make and retain records, in accordance with § 106.100(f)(1), of the frequency and results of testing of the water used in the production of infant formula.

(g) There shall be no backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for infant formula manufacturing.

(h) When steam comes in direct contact with infant formula, it shall be safe and free of rust and other particulate matter that may contaminate the formula. Boiler water additives in the steam shall be used in accordance with § 173.310 of this chapter.

(i) Each infant formula manufacturing site shall provide its employees with readily accessible toilet facilities and hand washing facilities that include hot and cold water, soap or detergent, and single-service towels and that are maintained in good repair and in a sanitary condition at all times, and that these facilities provide for proper disposal of the sewage. Doors to the toilet facility shall not open into areas where infant formula ingredients, containers, or closures are stored, or where infant formula is processed or stored.

§ 106.30 Controls to prevent adulteration caused by equipment or utensils.

(a) Equipment used in the manufacture, processing, packing or holding of an infant formula shall be of appropriate design and shall be installed to facilitate its intended function and its cleaning and maintenance.

(b) Equipment and utensils used in the manufacture, processing, packing, or holding of an infant formula shall be constructed so that surfaces that contact ingredients, in-process materials, or infant formula are made of nontoxic materials and are not reactive or absorptive. Such equipment and utensils shall be designed to be easily cleanable and to withstand the environment of their intended use. All surfaces that contact ingredients, in-process materials, or infant formula shall be cleaned, sanitized, and maintained to protect infant formula from being contaminated by any source. Sanitizing agents used on food-contact surfaces must comply with § 178.1010 of this chapter.

(c) Manufacturers shall ensure that substances, such as lubricants or coolants, that are required for operation of infant formula manufacturing equipment, but that would render the infant formula adulterated if they contaminated the formula, do not come in contact with formula ingredients, containers, closures, or in-process materials or with infant formula itself.

(d)(1) Manufacturers shall ensure that instruments used for measuring, regulating, or controlling mixing time and speed, temperature, pressure, moisture, water activity, or other parameters at points where control is deemed necessary to prevent adulteration in the processing of an infant formula are accurate, easily read, properly maintained, and present in sufficient number for their intended use. The instruments and controls shall be tested for accuracy (calibrated) against a known reference standard before first use and thereafter at routine intervals, as specified in writing by the manufacturer of the instrument or control, or as otherwise deemed necessary to ensure the accuracy of the instrument. The known reference standard shall be certified for accuracy at routine intervals specified in writing by the manufacturer of the instrument, or as otherwise deemed necessary to ensure the accuracy of the instrument. Manufacturers shall make and retain records of the accuracy checks in accordance with § 106.100(f)(2).

(2) Instruments and controls that cannot be adjusted to agree with the reference standard shall be repaired or replaced.

(3) If calibration of an instrument (testing for accuracy against a known reference standard) shows that a specification or standard for a point where control is deemed necessary to prevent adulteration has not been met, a written evaluation of all affected product, and of any actions that need to be taken with respect to that product, shall be made, in accordance with § 106.100(f)(2).

(e)(1) The temperature in cold storage compartments that are used to store raw materials, in-process materials, or final product, and in thermal processing equipment used at points where temperature control is necessary to prevent adulteration, shall be monitored with such frequency as is necessary to ensure that temperature control is maintained.

(2) Cold storage compartments shall be maintained at a temperature of 40 °F (4.4 °C) or below.

(3)(i) Cold storage compartments and thermal processing equipment shall be equipped with easily readable, accurate temperature-indicating devices.

(ii) Thermal processing equipment shall be equipped with temperature-recording devices that will reflect the true temperature on a continuing basis. Cold storage compartments shall be equipped with either temperature-recording devices that will reflect the true temperature, on a continuing basis, within the compartment or, in lieu of a temperature-recording device, a high temperature alarm or a maximum-indicating thermometer that has been verified to function properly. If the manufacturer uses either of the latter options, it shall maintain a temperature log in which it notes temperature with such frequency as is necessary to achieve control. Manufacturers shall make and retain records, in accordance with § 106.100(f)(3), of the temperatures indicated or recorded by these devices.

(4) When a temperature-recording device is used, such device shall not read higher than the calibrated temperature-indicating device for thermal processing equipment or lower than the reference temperature-indicating device for cold storage compartments.

(f) Equipment and utensils used in the manufacture of infant formula shall be cleaned, sanitized, and maintained at regular intervals to prevent adulteration of the infant formula. An individual qualified by training or experience to conduct such a review shall check all cleaning, sanitizing, and maintenance to ensure that it has been satisfactorily completed. Manufacturers shall make and retain records on equipment cleaning, sanitizing, and maintenance, in accordance with § 106.100(f)(4).

(g) Compressed air or other gases that are mechanically introduced into infant formula, that are used to clean any equipment, or that come into contact with any other surface that contacts ingredients, in-process materials, or infant formula shall be treated in such a way that their use will not contaminate the infant formula with unlawful indirect food additives or other chemical, physical, or microbiological contaminants. When compressed gases are used at product filling machines to replace air removed from the headspace of containers, the manufacturer shall install a 0.5 micrometer or smaller filter as close to the end of the gas line that feeds gas into the space, as practical.

§ 106.35 Controls to prevent adulteration due to automatic (mechanical or electronic) equipment.

(a)(1) For the purposes of this section, ''hardware'' means all automatic equipment, including mechanical and electronic equipment (including computers), that is used in production or quality control of a infant formula.

(2) For the purposes of this section, ''software'' means any programs, procedures, rules, and associated documentation used in the operation of a system.

(3) For the purposes of this section, ''system'' means a collection of components (including software and hardware) organized to accomplish a specific function or set of functions in a specified environment.

(4) For the purposes of this section, ''validation'' means establishing documented evidence that provides a high degree of assurance that a system will consistently produce a product meeting its predetermined specifications and quality characteristics.

(b)(1) All systems shall be designed, installed, tested, and maintained in a manner that will ensure that they are capable of performing their intended function and of producing or analyzing infant formula in accordance with this subpart and subpart C of this part.

(2) The infant formula manufacturer shall ensure that hardware is routinely calibrated, inspected, and checked according to written procedures.

(3) The infant formula manufacturer shall check and document the accuracy of input into, and output generated by, any system used in the production or quality control of an infant formula. The degree and frequency of input/output verification shall be based on the complexity and reliability of the system and the level of risk associated with the safe operation of the system.

(4) The infant formula manufacturer shall ensure that all systems are validated before their first use to manufacture commercial product.

(5) The infant formula manufacturer shall ensure that any system that is modified is revalidated after the modification and before use of the modified system to manufacture commercial product. All modifications to software shall be made by a designated individual and shall be checked by the infant formula manufacturer to ensure that infant formula that is produced or analyzed using the modified software complies with this subpart and with subpart C of this part.

(c) The infant formula manufacturer shall make and retain records, in accordance with § 106.100(f)(5), concerning automatic (mechanical or electronic) equipment.

§ 106.40 Controls to prevent adulteration caused by ingredients, containers, and closures.

(a) The only substances that may be used in infant formulas are food ingredients whose use in infant formula is safe and suitable under the applicable food safety provisions of the Federal Food, Drug, and Cosmetic Act; that is, the substance is generally recognized as safe (GRAS) for such use, is used in accordance with the agency's food additive regulations, or is authorized by a prior sanction.

(b) Infant formula containers and closures shall not be reactive or absorptive so as to affect the safety of the infant formula, and all packaging material that comes in contact with infant formula shall be composed of substances that are GRAS for use in or on food, GRAS for their intended use in food packaging, authorized by a prior sanction issued by the agency, or authorized for use as an indirect food additive. Any packaging material that comes in contact with infant formula shall be used in accordance with any prescribed limitations.

(c) Ingredients, containers, and closures used in the manufacture of infant formula shall be identified with a batch or lot number to be used in recording their disposition.

(d) Infant formula manufacturers shall develop written specifications for their acceptance or rejection of ingredients, containers, and closures used in infant formula manufacture. These specifications shall stipulate the standards for acceptance or rejection of such ingredients, containers, and closures as well as the procedures for determining whether the ingredients, containers, and closures meet that standard. An individual qualified by training or experience shall conduct an investigation of a finding that any ingredients, containers, or closures used in a batch of infant formula failed to meet any of the manufacturer's specifications.

(e) Ingredients, containers and closures shall be stored in areas clearly designated for:

(1) Materials pending release for use,

(2) Materials released for use, or

(3) Materials rejected for use in infant formula production. Any lot of ingredients, containers, or closures that does not meet the manufacturer's specifications shall be rejected and controlled under a quarantine system designed to prevent its use in the manufacture of infant formula.

(f) If an ingredient, a container, or a closure that has been tested and examined is exposed to air, heat, or other conditions that may adversely affect it, the ingredient, container, or closure shall be retested or reexamined to ensure that it still meets the manufacturer's specifications.

(g) Manufacturers shall make and retain records, in accordance with § 106.100(f)(6), on the ingredients, containers, and closures used in the manufacture of infant formula.

§ 106.50 Controls to prevent adulteration during manufacturing.

(a)(1) Manufacturers shall prepare and follow a written master manufacturing order that establishes controls and procedures for the production of an infant formula.

(2) The manufacturer shall make and retain records, in accordance with § 106.100(e), that include complete information relating to the production and control of the batch. An individual qualified by training or experience shall conduct an investigation of any

deviations from the master manufacturing order and any corrective actions taken.

(3) Changes made to the master manufacturing order shall be drafted, reviewed, and approved by a responsible official and include an evaluation of the effect of the change on the nutrient content and the suitability of the formula for infants.

(b) The manufacturer shall establish controls to ensure that each raw or in-process ingredient required by the master manufacturing order is examined by one person and checked by a second person or system. This checking will ensure that the correct ingredient is added during the manufacturing process, that the ingredient has been released for use in infant formula, and that the correct weight or measure of the ingredient is added to the batch.

(c) The manufacturer shall identify the contents, including the processing stage and the lot or batch number of a batch of infant formula, of all compounding and storage containers, processing lines, and major equipment used during the production of a batch of an infant formula.

(d) The manufacturer shall establish controls to ensure that the nutrient levels required by § 107.100 of this chapter are maintained in the formula, and that the formula is not contaminated with microorganisms or other contaminants. Such controls shall include but not be limited to:

(1) The mixing time; the speed, temperature, and flow rate of product; and other critical parameters necessary to ensure the addition of required ingredients to, and the homogeneity of, the formula;

(2) The spray-drying process for powdered infant formula, including the filtering of the intake air before heating, to prevent microbial and other contamination;

(3) The removal of air from the finished product to ensure that nutrient deterioration does not occur;

(4) Ensuring that each container of finished product is properly sealed. Such controls shall involve use of established procedures, specifications, and intervals of examination that are designed by qualified individuals and are sufficient to:

(i) Detect visible closure or seal defects, and

(ii) Determine closure strength through destructive testing. Manufacturers of liquid infant formulas, which are thermally processed low-acid foods packaged in hermetically sealed containers, shall perform such closure integrity testing in accordance with § 113.60(a) of this chapter.

(e) The manufacturer shall establish controls that ensure that the equipment used at points where control is deemed necessary to prevent adulteration is monitored, so that personnel will be alerted to malfunctions.

(f) The manufacturer shall establish controls that ensure that rejected in-process materials:

(1) Are clearly identified as having been rejected for use in an infant formula;

(2) Are controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable;

(3) Meet the appropriate specifications, if reprocessed, before being released for use in infant formula.

§ 106.55 Controls to prevent adulteration from microorganisms.

(a) Manufacturers of liquid infant formula shall comply with the procedures specified in part 113 of this chapter for liquid infant formula.

(b) Manufacturers of powdered infant formula shall test representative samples of every batch of the formula at the final product stage, before distribution, to ensure that the infant formula meets the microbiological quality standards listed in paragraph (c) of this section.

(c) Any powdered infant formula that contains any microorganism that exceeds the M value listed for that microorganism in Table 1 of this section will be deemed to be adulterated under sections 402 and 412 of the Federal Food, Drug, and Cosmetic Act (the act). FDA will determine compliance with the M values listed below using the *Bacteriological Analytical Manual* (BAM), 8th ed. (1995), published by the AOAC International Association of Official Analytical Chemists, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Association of Official Analytical Chemists, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or may be examined at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

Microorganism	M value [1]
Aerobic Plate Count (APC).	10,000 CFU/gram (g). [2]
Coliforms [3]	3.05 MPN/g. [4,5]
Fecal coliforms [6]	3.05 MPN/g.
Salmonella	0. [7]
Listeria monocytogenes.	0. [7]
Staphylococcus aureus.	3.05 MPN/g.
Bacillus cereus [8]	100 MPN/g or CFU/g.

[1] The M value is the maximum allowable number of microorganisms present in 1 g of dry infant formula.

[2] CFU/g, colony forming units per g.

[3] M values for coliforms greater than 3.05 are not violative if testing for fecal coliforms results in an M value equal to or less than 3.05.

[4] MPN/g, most probable number per g.

[5] The MPN value of 3.05 in this table is derived from the tables of calculated MPN values that appear in the 8th ed. of the BAM when using an inoculation series of 0.1, 0.01, and 0.001g (or ml) of the infant formula sample.

[6] No testing for fecal coliforms is required when the M value for coliforms is less than or equal to 3.05.

[7] None detected.

[8] *B. cereus* testing must be performed only if the APC exceeds 100 CFU/g.

(d) Manufacturers shall make and retain records, in accordance with § 106.100(e)(5)(ii) and (f)(7), on the testing of infant formulas for microorganisms.

§ 106.60 Controls to prevent adulteration during packaging and labeling of infant formula.

(a) Manufacturers shall examine packaged and labeled infant formula during finishing operations to ensure that containers and packages in the lot have the correct label, the correct use-by date, and the correct code established under § 106.80.

(b) Labels shall be designed, printed, and applied so that the labels remain legible and attached during the conditions of processing, storage, handling, distribution, and use.

(c) All infant formula held in a single package shall be the same product bearing the same code, established under § 106.80. Packaging used to hold multiple containers of infant formula shall be labeled with the product name, the name of the manufacturer or shipper, and the code.

§ 106.70 Controls on the release of finished infant formula.

(a) The manufacturer shall hold, or maintain under its control, each batch of infant formula until it determines that the batch meets all of its specifications, including those adopted to meet the requirements of § 106.55 on microbiological contamination and § 106.91(a) on quality control procedures, and releases the batch for distribution.

(b) Each batch of infant formula that fails to meet the manufacturer's specifications shall be rejected. Although the batch may be reprocessed, any batch of infant formula that is reprocessed shall be shown to meet the

requirements of § 106.70(a) before it is released.

(c) An individual qualified by training or experience shall conduct an investigation of a finding that a batch of infant formula fails to meet any manufacturer's specifications.

§ 106.80 Traceability.

(a) Manufacturers shall ensure traceability by coding infant formulas in conformity with the coding requirements prescribed in § 113.60(c) of this chapter for thermally processed low-acid foods packaged in hermetically-sealed containers, except as provided in paragraph (b) of this section.

(b) Batches of powdered infant formula that are manufactured in stages over more than 1 day, in lieu of being coded in accordance with § 113.60(c) of this chapter, may be coded with a sequential number that identifies the product and the establishment where the product was packed and that permits tracing of all stages of manufacture of that batch, including the year, the days of the year, and the period during those days that the product was packed, and the receipt and handling of raw materials used.

§ 106.90 Audits of current good manufacturing practice.

Manufacturers of an infant formula, or an agent of such manufacturers, shall conduct regularly scheduled audits to determine whether the manufacturer has complied with the current good manufacturing practice regulations in this subpart. These audits shall be performed by an individual who, as a result of education, training, and experience, is knowledgeable in all aspects of infant formula production and of the agency's regulations concerning current good manufacturing practice but who has no direct responsibility for the matters being audited.

Subpart C—Quality Control Procedures

§ 106.91 General quality control.

(a) *Nutrient testing to ensure that each batch of infant formula provides nutrients in accordance with § 107.100.* Manufacturers shall test each batch as follows:

(1) Each nutrient premix used in the manufacture of an infant formula shall be tested for each nutrient that the manufacturer is relying on the premix to provide to ensure that the premix is in compliance with the manufacturer's specifications;

(2) During the manufacturing process, after the addition of the premix, or at the final-product-stage but before distribution, each batch of infant formula shall be tested for at least one indicator nutrient for each of the nutrient premixes used in the infant formula to confirm that the nutrients supplied by each of the premixes are present, in the proper concentration, in the batch of infant formula.

(3) At the final-product-stage, before distribution of an infant formula, each batch shall be tested for vitamins A, C, E, and thiamin.

(4) During the manufacturing process or at the final-product-stage, before distribution, each batch shall be tested for all nutrients required to be included in such formula under § 107.100 of this chapter and for any nutrient added by the manufacturer for which testing is not conducted for compliance with paragraphs (a)(1) or (a)(3) of this section.

(b) *Stability testing.* Every 3 months, manufacturers shall collect representative samples from the final-product-stage of one batch of each physical form (powder, ready-to-feed, or concentrate) of each infant formula, at each manufacturing facility. The manufacturer shall test these samples for each nutrient required under § 107.100 of this chapter and for any nutrient added by the manufacturer. The frequency of such testing shall be at the beginning, midpoint, and end of the shelf life of the infant formula and, depending on the nutrient and its stability within the matrix of the formulation, with additional frequency as is necessary to ensure that such formula complies with section 412 of the Federal Food, Drug, and Cosmetic Act (the act) throughout the shelf life of the infant formula; except that:

(1) If the infant formula is a new infant formula, manufacturers shall collect a representative sample from the final-product-stage of each physical form (powder, ready-to-feed, or concentrate) of the first batch of the new infant formula and test these samples according to the requirements of this section; and

(2) If an infant formula has been changed in formulation or in processing in a way that does not make it a new infant formula but that may affect whether it is adulterated under section 412(a) of the act, the manufacturer shall collect a representative sample from the final-product-stage of each physical form (powder, ready-to-feed, or concentrate) of the first batch of the infant formula and shall test these samples according to the frequency required by this section for each nutrient that has been or may have been affected by the change.

(c) *Quality control records.* Manufacturers shall make and retain quality control records in accordance with § 106.100(e)(5)(i) and (f)(7).

§ 106.92 Audits of quality control procedures.

A manufacturer of an infant formula, or an agent of such a manufacturer, shall conduct regularly scheduled audits to determine whether the manufacturer has complied with the quality control procedures that are necessary to ensure that an infant formula provides nutrients in accordance with section 412(b) and (i) of the Federal Food, Drug, and Cosmetic Act and is manufactured in a manner designed to prevent adulteration of the infant formula under section 412(a)(1) and (a)(3) of the Federal Food, Drug, and Cosmetic Act. These audits shall be performed by an individual who, as a result of education, training, and experience, is knowledgeable in all aspects of infant formula production and of the agency's regulations concerning quality control procedures but who has no direct responsibility for the matters being audited.

Subpart D—Conduct of Audits

§ 106.94 Audit plans and procedures.

(a) Manufacturers shall develop and follow a written audit plan that is available at the manufacturing facility for FDA inspection.

(b) The audit plan shall include audit procedures that set out the methods the manufacturer uses to determine whether the facility is operating in accordance with current good manufacturing practice, with the quality control procedures that are necessary to assure that an infant formula provides nutrients in accordance with section 412(b) and (i) of the Federal Food, Drug, and Cosmetic Act, and in a manner designed to prevent adulteration of the infant formula.

(c) The audit procedures shall include, but not be limited to:

(1) An evaluation of the production and in-process control system established under § 106.6(b) by:

(i) Observing the production of infant formula and comparing the observed process to the written production and in-process control plan required under § 106.6(b);

(ii) Reviewing records of the monitoring of points, steps, or stages where control is deemed necessary to prevent adulteration; and

(iii) Reviewing records of how deviations from any standard or specification at points, steps, or stages where control is deemed necessary to prevent adulteration were handled; and

(2) A review of a representative sample of all records maintained in accordance with § 106.100(e) and (f).

Subpart E—Quality Factors for Infant Formulas

§ 106.96 Quality factors in infant formulas.

(a) All infant formulas shall, when fed to infants as a sole source of nutrition, be of sufficient quality to meet the nutritional requirements for healthy growth. The regulations set forth in this subpart define the minimum quality factors for infant formulas.

(b) All infant formulas shall be capable of supporting normal physical growth of infants.

(c) All infant formulas shall be formulated and manufactured such that the protein is of sufficient biological quality to meet the protein requirements of infants.

§ 106.97 Assurances for quality factors.

(a) *General quality factor of normal physical growth.* (1) The manufacturer shall conduct an adequate and well-controlled clinical study, in accordance with good clinical practice, to determine whether an infant formula supports normal physical growth in infants when the formula is fed as the sole source of nutrition.

(i) The manufacturer shall:

(A) Conduct a clinical study that is no less than 4 months in duration, enrolling infants no more than 1 month old at time of entry into the study.

(B) Collect and maintain data in the study on anthropometric measures of physical growth, including body weight, recumbent length, head circumference, and average daily weight increment, and plot the data on National Center for Health Statistics (NCHS) reference percentile body weight and body length curves. The NCHS growth charts are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Constituent Operations (HFS–565), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, may be examined at the Office of Special Nutritionals (HFS–456), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(C) Collect anthropometric measurements at the beginning of the clinical study, at 2 weeks, at 4 weeks, at least monthly thereafter, and at the conclusion of the study.

(ii) The clinical study protocol should:

(A) Describe the scientific basis and objectives of the study, the planned control and treatment feeding regimens, the entrance criteria used to enroll infants in the study, the method of randomization used for the assignment of infants to feeding groups, the collection of specific measurements and other data, the methods used to limit sources of bias, and the planned methods of statistical analysis;

(B) Describe the necessary qualifications and experience of investigators;

(C) Be reviewed and approved by an Institutional Review Board (IRB) in accordance with part 56 of this chapter. The manufacturer shall establish procedures to obtain written informed consent from parents or legal representatives of the infants enrolled in the study in accordance with part 50 of this chapter;

(D) Explain how the study population represents the population for which the new infant formula is intended and how the study addresses the intended conditions of use of the formula.

(E) Describe the sample size calculations and the power calculations and the basis for selecting the sample size and study design;

(F) Describe the plan to identify and evaluate any adverse effects;

(G) Describe the quality control procedures used to ensure the validity and reliability of the measurements collected.

(H) Describe and compare the composition of the test and control formulas.

(I) Describe the basis upon which the test formula is appropriate for use in evaluating the formula that the manufacturer intends to market, if the test formula used in a study is not identical to the formula that is intended to be marketed in the United States.

(2) The manufacturer may request an exemption from the requirements of paragraph (a)(1) of this section if:

(i) The manufacturer has similar experience using an ingredient, an ingredient mixture, or a processing method in the production of an infant formula marketed in the United States and can demonstrate that infant formula made with that ingredient, ingredient mixture, or processing method meets the quality factor requirements in § 106.96;

(ii) The manufacturer markets a formulation in more than one form (e.g., liquid and powdered forms) and can demonstrate that the quality factor requirements are met by the form of the formula that is processed using the method that has the greatest potential for adversely affecting nutrient content and bioavailability;

(iii) The manufacturer can demonstrate that the requirements of paragraph (a)(1) of this section are not appropriate for evaluation of a specific infant formula, and that an alternative method or study design for showing that the formula supports healthy growth in infants fed it as their sole source of nutrition is available.

(b) *Specific quality factor for protein quality of infant formula.* (1) The manufacturer shall collect and maintain data that establish that the biological quality of protein in an infant formula is sufficient to meet the protein requirements of infants. The manufacturer shall establish the biological quality of the protein in its infant formula by demonstrating that the protein source supports adequate growth using the Protein Efficiency Ratio (PER) rat bioassay described in the ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 16th ed., sections 43.3.04 and 43.3.05, ''AOAC Official Method 960.48 Protein Efficiency Ratio Rat Bioassay'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Association of Official Analytical Chemists, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20857, or the Office of Special Nutritionals (HFS–456), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be examined at the Office of the Federal Register, 800 North Capitol St. NW., Washington, DC. If the manufacturer is unable to conduct a PER rat bioassay because of the composition of the protein in the formula, then it shall demonstrate that the amino acid composition of the protein meets the known amino acid requirements of infants for whom the formula is intended.

(2) The manufacturer may request an exemption from the requirements of paragraph (b)(1) of this section if:

(i) The protein source, including any processing method used to produce the protein source, is already used in another infant formula marketed in the United States, manufactured by the same manufacturer, and the manufacturer can demonstrate that such infant formula meets the quality factor requirements prescribed in § 106.96;

(ii) The protein source, including any processing methods used to produce the protein source, is not a major change from the infant formula it replaces, and the manufacturer can demonstrate that the infant formula it replaces meets the

quality factor requirements prescribed in § 106.96.

6. In newly redesignated subpart F, § 106.100 is amended by revising paragraphs (e), (f), (g), (j), and (k)(3), and by removing and reserving paragraph (h) to read as follows:

§ 106.100 Records.

* * * * *

(e) *Batch production and control records.* For each batch of infant formula, manufacturers shall prepare and maintain records that include complete information relating to the production and control of the batch. These records shall include but are not limited to:

(1) The master manufacturing order. The master manufacturing order shall include but is not limited to:

(i) The significant steps in the production of the batch and the date on which each significant step occurred;

(ii) The identity of equipment and processing lines used in producing the batch, if the plant in which the formula is made includes more than one set of equipment or more than one processing line;

(iii) The identity of each batch or lot of ingredients, containers, and closures used in producing the batch of formula;

(iv) The amount of each ingredient to be added to the batch of infant formula and a check (verification) that the correct amount was added; and

(v) Copies of all labeling used and the results of examinations conducted during the finishing operations to provide assurance that containers and packages in the lot have the correct label.

(2) Any deviations from the master manufacturing order and any corrective actions taken because of the deviations.

(3) Documentation, in accordance with § 106.6(c), of the monitoring at any point, step, or stage in their production process where control is deemed necessary to prevent adulteration. These records shall include, but not be limited to:

(i) A list of the standards or specifications established at each point, step, or stage in their production process where control is deemed necessary to prevent adulteration including documentation of the scientific basis for each standard or specification;

(ii) The actual values obtained during the monitoring operation, any deviations from established standards or specifications, and any corrective actions taken;

(iii) Identification of the person monitoring each point, step, or stage in their production process where control is deemed necessary to prevent adulteration.

(4) The conclusions and followup, along with the identity, of the individual qualified by training or experience who investigated:

(i) Any deviation from the master manufacturing order and any corrective actions taken;

(ii) A finding that a batch or any of its ingredients failed to meet the infant formula manufacturer's specifications; and

(iii) A failure to meet any specification or standard at any point, step, or stage in the production process where control is deemed necessary to prevent adulteration.

(5) The results of all testing performed on the batch of infant formula, including testing on the in-process batch, at the final-product stage, and on finished product throughout the shelf life of the product. The results recorded shall include but are not limited to:

(i) The results of all quality control testing conducted, in accordance with § 106.91(a) and (b), to verify that each nutrient required by § 107.100 of this chapter is present in each batch of infant formula at the level required by § 107.100, and that any nutrient added by the manufacturer is present at the appropriate level with:

(A) A summary table identifying the stages of the manufacturing process at which the nutrient analysis for each required nutrient under § 106.91(a) is conducted, and

(B) A summary table on the stability testing program, including the nutrients tested and the frequency of testing of nutrients throughout the shelf life of the product under § 106.91(b); and

(ii) For powdered infant formula, the results of any testing conducted in accordance with § 106.55(b) to verify compliance with the microbiological quality standards in § 106.55(c).

(f) Manufacturers shall make and retain all records pertaining to current good manufacturing practice as described in subpart B of this part, including but not limited to:

(1) Records, in accordance with § 106.20(f)(3), of the frequency and results of testing of the water used in the production of infant formula;

(2) Records, in accordance with § 106.30(d), of accuracy checks of instruments and controls. A certification of accuracy of any known reference standard used and a history of recertification shall be maintained. At a minimum, such records shall specify the instrument or control being checked, the date of the accuracy check, the standard used, the calibration method used, the results found, any actions taken if the instrument is found to be out of calibration, and the initials or name of the individual performing the test. If calibration of an instrument (testing for accuracy against a known reference standard) shows that a specification or standard at a point, step, or stage in the production process where control is deemed necessary to prevent adulteration has not been met, a written evaluation of all affected product, and any actions that need to be taken with respect to that product, shall be made.

(3) Records, in accordance with § 106.30(e)(3)(ii), of the temperatures monitored for cold storage compartments and thermal processing equipment.

(4) Records, in accordance with § 106.30(f), on equipment cleaning, sanitizing, and maintenance that show the date and time of such cleaning, sanitizing, and maintenance and the lot number of each batch of infant formula processed between equipment startup and shutdown for cleaning, sanitizing, and maintenance. The person performing and checking the cleaning, sanitizing, and maintenance shall date and sign or initial the record indicating that the work was performed.

(5) Records, in accordance with § 106.35(c), on all automatic (mechanical or electronic) equipment used in the production or quality control of infant formula. These records shall include but not be limited to:

(i) A list of all systems used with a description of computer files and the inherent limitations of each system;

(ii) A copy of all software used;

(iii) Records that document installation, calibration, testing or validation, and maintenance of the systems used;

(iv) A list of all persons authorized to create or modify software;

(v) Records that document modifications to software, including the identity of the person who modified the software;

(vi) Records that document retesting or revalidation of modified systems; and

(vii) A backup file of data entered into a computer or related system. The backup file shall consist of a hard copy or alternative system, such as duplicate diskettes, tapes, or microfilm, designed to ensure that backup data are exact and complete, and that they are secure from alteration, inadvertent erasures, or loss.

(6) Records, in accordance with § 106.40(g), on ingredients, containers, and closures used in the manufacture of infant formula. These records shall include, but are not limited to:

(i) The identity and quantity of each lot of ingredients, containers, and closures;

(ii) The name of the supplier;

(iii) The supplier's lot numbers;

(iv) The name and location of the manufacturer of the ingredient, container, and closure, if different from the supplier;

(v) The date of receipt;

(vi) The receiving code as specified; and

(vii) The results of any test or examination (including retesting and reexamination) performed on the ingredients, containers, and closures and the conclusions derived therefrom and the disposition of all ingredients, containers, or closures.

(7) A full description of the methodology used to test powdered infant formula to verify compliance with the microbiological quality standards of § 106.55(c) and the methodology used to do quality control testing, in accordance with § 106.91(a) and (b).

(g) The manufacturer shall maintain all records pertaining to distribution of the infant formula, including records that show that products produced for export only are exported. Such records shall include, but not be limited to, all information and data necessary to effect and monitor recalls of the manufacturer's infant formula products in accordance with subpart E of part 107 of this chapter.

(h) [Reserved]

* * * * *

(j) The manufacturer shall make and retain records pertaining to regularly scheduled audits, including the audit plans and procedures, the findings of the audit, and a listing of any changes made in response to these findings. The manufacturer shall make readily available for authorized inspection the audit plans and procedures and a statement of assurance that the regularly scheduled audits are being conducted. The findings of the audit and any changes made in response to these findings shall be maintained for the time period required under § 106.100(n), but need not be made available to FDA.

(k) * * *

(3) When there is a reasonable possibility of a causal relationship between the consumption of an infant formula and an infant's death, the manufacturer shall, within 15 days of receiving such information, conduct an investigation and notify the agency as required in § 106.150.

* * * * *

Subpart G—Registration, Submission, and Notification Requirements

§ 106.110 New infant formula registration.

(a) Before a new infant formula may be introduced or delivered for introduction into interstate commerce, the manufacturer of such formula shall register with the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Special Nutritionals, Division of Programs and Policy Enforcement (HFS–455), Infant Formula Coordinator, 200 C St. SW., Washington, DC 20204. An original and two copies of this registration shall be submitted.

(b) The new infant formula registration shall include:

(1) The name of the new infant formula,

(2) The name of the manufacturer,

(3) The place of business of the manufacturer, and

(4) All establishments at which the manufacturer intends to manufacture such new infant formula.

§ 106.120 New infant formula submission.

(a) At least 90 days before a new infant formula is introduced or delivered for introduction into interstate commerce, a manufacturer shall submit notice of its intent to do so to the Food and Drug Administration at the address given in § 106.110(a). An original and two copies of the notice of its intent to do so shall be submitted.

(b) The new infant formula submission shall include:

(1) The name and physical form (e.g., powder, ready-to feed, or concentrate) of the infant formula;

(2) An explanation of why the formula is a new infant formula;

(3) The quantitative formulation of each form of the infant formula that is the subject of the notice in units per volume (for liquid formulas) or units per dry weight (for powdered formulas). When applicable, the submission shall include a description of any reformulation of the infant formula, including a listing of each new or changed ingredient and a discussion of the effect of such changes on the nutrient levels in the formulation;

(4) A description, when applicable, of any change in processing of the infant formula. Such description shall identify the specific change in processing, including side-by-side, detailed schematic diagrams comparing the new processing to the previous processing (including processing times and temperatures);

(5) Assurance that the infant formula will not be marketed unless the formula meets the quality factor requirements of section 412(b)(1) of the Federal Food, Drug, and Cosmetic Act (the act) and the nutrient content requirements of section 412(i) of the act.

(i) Assurance that the formula meets the quality factor requirements, which are set forth in subpart E of this part, shall be provided by a submission that complies with § 106.121.

(ii) Assurance that the formula complies with the nutrient content requirements, which are set forth in § 107.100 of this chapter, shall be provided by a statement assuring that the formula will not be marketed unless it meets the nutrient requirements of § 107.100 of this chapter, as demonstrated by testing required under subpart C of this part;

(6) Assurance that the processing of the infant formula complies with section 412(b)(2) of the act. Such assurance shall include but not be limited to:

(i) A statement that the formula will be produced in accordance with subparts B and C of this part;

(ii) The basis on which each ingredient meets the requirements of § 106.40(a), e.g., that it is an approved food additive, that it is authorized by a prior sanction issued by the agency, or that it is GRAS for its intended use. Any claim that an ingredient is GRAS shall be supported by a citation to the agency's regulations or by an explanation, including a list of published studies and a copy of those publications, for why, based on the published studies, there is general recognition of the safety of the use of the ingredient in infant formula.

(c) For products for export only, a manufacturer may submit, in lieu of the information required under paragraph (b) of this section, a statement that the infant formula meets the specifications of the foreign purchaser, does not conflict with the laws of the country to which it is intended for export, is labeled on the outside of the shipping package to indicate that it is intended for export only, and will not be sold or offered for sale in domestic commerce.

(d) The submission will not constitute notice under section 412 of the act unless it complies fully with paragraph (b) of this section, and the information that it contains is set forth in a manner that is readily understandable. The agency will notify the submitter if the notice is not adequate because it does not meet the requirements of section 412(c) and (d) of the act.

(e) If a new infant formula submission is adequate, FDA will acknowledge its receipt and notify the manufacturer of the date of receipt. The date that the agency receives the new infant formula

submission is the filing date for the submission. The manufacturer shall not market the new infant formula before the date that is 90 days after the filing date.

(f) If the manufacturer provides additional information in support of a new infant formula submission, the agency will determine whether the additional information is a substantive amendment to the new infant formula submission. If the agency determines that the new submission is a substantive amendment, FDA will assign the new infant formula submission a new filing date. FDA will acknowledge receipt of the additional information and, when applicable, notify the manufacturer of the new filing date, which is the date of receipt by FDA of the information that constitutes the substantive amendment to the new infant formula submission.

§ 106.121 Quality factor submission.

To provide assurance that an infant formula meets the quality factor requirements set forth in subpart E of this part, the manufacturer shall submit the following data and information:

(a) An explanation, in narrative form, setting forth how all quality factor requirements of subpart E of this part have been met.

(b) Records that contain the information required by proposed § 106.97 (a)(1)(i) and (a)(1)(ii) collected during the study for each infant enrolled in the study. The records shall be identified by subject number, age, feeding group, gender, and study day of collection.

(c)(1) Statistical evaluation for all measurements, including: Group means, group standard deviations, and measures of statistical significance for all measurements for each feeding group at the beginning of the study and at every point where measurements were made throughout the study.

(2) Calculation of the statistical power of the study at its completion.

(d) A report on attrition and on all occurrences of adverse events during the study, which shall include:

(1) Identification of the infant by subject number and feeding group and a complete description of the adverse event, including comparisons of the frequency and nature of occurrence in each feeding group and information on the health of the infant during the course of the study, including the occurrence and duration of any illness;

(2) A clinical assessment, by a health care provider, of the infant's health during each suspected adverse event;

(3) A complete listing of all infants who did not complete the study, including the infant's subject number and the reason that each infant left the study.

(e) The results of the Protein Efficiency Ratio, in accordance with § 106.97(b).

(f) A statement certifying that the manufacturer has collected and considered all information and data concerning the ability of the infant formula to meet the quality factor requirements, and that the manufacturer is not aware of any information or data that would show that the formula does not meet the quality factors requirements.

§ 106.130 Verification submission.

(a) Manufacturers shall, after the first production and before the introduction into interstate commerce of the new infant formula, verify in a written submission to FDA at the address given in § 106.110(a), that the infant formula complies with the requirements of the Federal Food, Drug, and Cosmetic Act (the act) and is not adulterated. An original and two copies of this verification shall be submitted.

(b) The verification submission shall include the following information:

(1) The name of the new infant formula; the filing date for the new infant formula submission, in accordance with § 106.120, for the subject formula; and the identification number assigned by the agency to the new infant formula submission;

(2) A statement that the infant formula to be introduced into interstate commerce is the same as the infant formula that was the subject of the new infant formula notification and for which the manufacturer provided assurances in accordance with the requirements of § 106.120;

(3) A summary of test results of the level of each nutrient required by § 107.100 of this chapter and any nutrient added by the manufacturer in the formula, presented in units per 100 kilocalories at the final-product-stage.

(4) A certification that the manufacturer has established current good manufacturing practices including quality control procedures and in-process controls, including testing required by current good manufacturing practice, designed to prevent adulteration of this formula in accordance with subparts B and C of this part.

(c) The submission will not constitute written verification under section 412(d)(2) of the act when any data prescribed in paragraph (b) of this section are lacking or are not set forth so as to be readily understood. In such circumstances the agency will notify the submitter that the notice is not adequate.

§ 106.140 Submission concerning a change in infant formula that may adulterate the product.

(a) When a manufacturer makes a change in the formulation or processing of the formula that may affect whether the formula is adulterated under section 412(a) of the Federal Food, Drug, and Cosmetic Act (the act), it shall, before the first processing of such formula, make a submission to the Food and Drug Administration at the address given in § 106.110(a). An original and two copies shall be submitted.

(b) The submission shall include:

(1) The name and physical form of the infant formula (i.e., powder, ready-to-feed, or concentrate);

(2) An explanation of why the change in formulation or processing may affect whether the formula is adulterated; and

(3) A submission that complies with § 106.120(b)(3), (b)(4), (b)(5), and (b)(6). When appropriate, a statement to the effect that the information required by § 106.120(b)(3), (b)(4), (b)(5), or (b)(6) has been provided to the agency previously and has not been affected by the changes that is the subject of this submission, together with the identification number assigned by the agency to the relevant infant formula submission, may be provided in lieu of such submission.

(c) The submission will not constitute notice under section 412 of the act unless it complies fully with paragraph (b) of this section, and the information that it contains is set forth in a manner that is readily understandable. The agency will notify the submitter if the notice is not adequate because it does not meet the requirements of section 412(d)(3) of the act.

§ 106.150 Notification of an adulterated or misbranded infant formula.

(a) A manufacturer shall promptly notify FDA in accordance with paragraph (b) of this section, when the manufacturer has knowledge (that is, the actual knowledge that the manufacturer had, or the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the exercise of due care) that reasonably supports the conclusion that an infant formula that has been processed by the manufacturer and that has left an establishment subject to the control of the manufacturer:

(1) May not provide the nutrients required by section 412(i) of the act or by regulations issued under section 412(i)(2); or

(2) May be otherwise adulterated or misbranded.

(b) The notification made according to paragraph (a) of this section shall be made by telephone, to the Director of the appropriate Food and Drug Administration district office. After normal business hours (8 a.m. to 4:30 p.m.), FDA's emergency number, 202–857–8400, shall be used. The manufacturer shall send written confirmation of the notification to the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Special Nutritionals, Division of Programs and Policy Enforcement (HFS–455), Infant Formula Coordinator, 200 C St. SW., Washington, DC 20204, and to the appropriate Food and Drug Administration district office specified in § 5.115 of this chapter.

PART 107—INFANT FORMULA

7. The authority citation for 21 CFR part 107 continues to read as follows:

Authority: Secs. 201, 403, 412, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 343, 350a, 371).

8. Section 107.1 is added to subpart A to read as follows:

§ 107.1 Status and applicability of the regulations in part 107.

(a) The criteria set forth in subpart B of this part describes the labeling requirements applicable to infant formula under section 403 of the Federal Food, Drug, and Cosmetic Act (the act). Failure to comply with any regulation in subpart B of this part will render an infant formula misbranded under that section of the act.

(b) The criteria set forth in subpart C of this part describes the terms and conditions for the exemption of an infant formula from the requirements of section 412(a), (b), and (c) of the act. Failure to comply with any regulations in subpart C of this part will result in the withdrawal of the exemption given under section 412(h)(1) of the act.

(c) Subpart D of this part sets forth the nutrient requirements for infant formula under section 412(i) of the act. Failure to comply with any regulation in subpart D of this part will render an infant formula adulterated under section 412(a)(1) of the act.

9. Section 107.10 is amended by revising the introductory text of paragraph (a)(2) to read as follows:

§ 107.10 Nutrient information.

(a) * * *

(2) A statement of the amount, supplied by 100 kilocalories, of each of the following nutrients and of any nutrient added by the manufacturer:

* * * * *

10. Section 107.240 is revised to read as follows:

§ 107.240 Notification requirements.

(a) *Telephone report.* When a determination is made that an infant formula is to be recalled, the recalling firm shall telephone within 24 hours the appropriate Food and Drug Administration district office listed in § 5.115 of this chapter and shall provide relevant information about the infant formula that is to be recalled.

(b) *Initial written report.* Within 14 days after the recall has begun, the recalling firm shall provide a written report to the appropriate Food and Drug Administration district office. The report shall contain relevant information, including the following cumulative information concerning the infant formula that is being recalled:

(1) Number of consignees notified of the recall and date and method of notification, including recalls required by § 107.200, information about the notice provided for retail display and the request for its display.

(2) Number of consignees responding to the recall communication and quantity of recalled infant formula on hand at the time it was received.

(3) Quantity of recalled infant formula returned or corrected by each consignee contacted and the quantity of recalled infant formula accounted for.

(4) Number and results of effectiveness checks that were made.

(5) Estimated timeframes for completion of the recall.

(c) *Status reports.* The recalling firm shall submit to the appropriate Food and Drug Administration district office a written status report on the recall at least every 14 days until the recall is terminated. The status report shall describe the steps taken by the recalling firm to carry out the recall since the last report and the results of these steps.

11. Section 107.250 is amended by revising the introductory text to read as follows:

§ 107.250 Termination of an infant formula recall.

The recalling firm may submit a recommendation for termination of the recall to the appropriate Food and Drug Administration district office listed in § 5.115 of this chapter for transmittal to the Division of Enforcement (HFS–605), Office of Field Programs, Center for Food Safety and Applied Nutrition, for action. Any such recommendation shall contain information supporting a conclusion that the recall strategy has been effective. The agency will respond within 15 days of receipt by the Division of Enforcement (HFS–605), Office of Field Programs, Center for Food Safety and Applied Nutrition, of the request for termination. The recalling firm shall continue to implement the recall strategy until it receives final written notification from the agency that the recall has been terminated. The agency will send such notification, unless it has information, from FDA's own audits or from other sources demonstrating the recall has not been effective. The agency may conclude that a recall has not been effective if:

* * * * *

Dated: April 19, 1996.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 96–17058 Filed 7–8–96; 8:45 am]

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Part IV

Department of Energy

10 CFR Part 1021

National Environmental Policy Act Implementing Procedures; Final Rule

DEPARTMENT OF ENERGY

10 CFR Part 1021

RIN 1901–AA67

National Environmental Policy Act Implementing Procedures

AGENCY: Department of Energy.

ACTION: Final rule.

SUMMARY: The Department of Energy (DOE) is amending its existing regulations governing compliance with the National Environmental Policy Act (NEPA). The amendments incorporate changes that improve DOE's efficiency in implementing NEPA requirements by reducing costs and preparation time while maintaining quality, consistent with the DOE Secretarial Policy Statement on NEPA issued in June 1994. These amendments also incorporate changes necessary to conform to recent changes in DOE's missions, programs, and policies that have evolved in response to changing national priorities since the current regulations were issued in 1992.

EFFECTIVE DATE: These amendments to the rule will become effective August 8, 1996.

FOR FURTHER INFORMATION CONTACT: Carol Borgstrom, Director, Office of NEPA Policy and Assistance, EH–42, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585–0119, (202) 586–4600 or leave a message at (800) 472–2756.

SUPPLEMENTARY INFORMATION:

I. Background

The National Environmental Policy Act of 1969 (42 USC 4321 *et seq.*) requires that Federal agencies prepare environmental impact statements for major Federal actions that may ''significantly affect the quality of the human environment.'' NEPA also created the President's Council on Environmental Quality (CEQ), which issued regulations in 1978 implementing the procedural provisions of NEPA. Among other requirements, the CEQ NEPA regulations (40 CFR parts 1500–1508) require Federal agencies to adopt their own implementing procedures to supplement the Council's regulations. DOE's current NEPA implementing regulations were promulgated in 1992 (57 FR 15122, April 24, 1992) and are codified at 10 CFR part 1021.

On February 20, 1996, DOE published a proposed rulemaking that would revise its existing NEPA implementing regulations (61 FR 6414). Publication of the Notice of Proposed Rulemaking began a 45-day public comment period that originally ended on April 5, 1996. In response to requests, the comment period was subsequently reopened on April 19, 1996 (61 FR 17257), and extended until May 10, 1996. As part of the notice and comment process and also in response to requests, DOE held a public hearing on the proposed amendments on May 6, 1996. Comments were received from approximately 39 sources, including Federal and state agencies, public interest groups, other organizations, and individuals. Seven commenters also spoke at the public hearing. Copies of all written comments and the transcript of the public hearing have been provided to CEQ and are available for public inspection at the DOE Freedom of Information Reading Room, Room 1E–190, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–6020.

The amendments revise subparts A, C and D of the existing regulations. Among the changes are various revisions to the lists of ''typical classes of actions'' (appendices A, B, C, and D to subpart D), including the addition of new categorical exclusions, modifications that expand or remove existing categorical exclusions, and clarifications. Other changes pertain to the DOE requirement for an implementation plan for each environmental impact statement and DOE's required content for findings of no significant impact. DOE is also clarifying its public notification requirements for records of decisions.

DOE is continuing to consider its proposed amendments to subpart D that relate to the Federal power marketing administrations. Accordingly, as described in a separate Notice published elsewhere in this issue, DOE will reopen the public comment period on the proposed amendments to subpart D that apply primarily to power marketing activities (B4.1, B4.2, B4.3, B4.6, B4.10, B4.11, B4.12, B4.13, C4, C7, and D7). This final rule addresses the remainder of the proposed amendments.

This Notice adopts the amendments proposed in the Notice of Proposed Rulemaking (except for the power marketing classes of actions listed above), with certain changes discussed below, and amends the existing regulations at 10 CFR Part 1021. Copies of the final amendments to the rule are available upon request from the information contact listed above.

In accordance with the CEQ NEPA regulations, 40 CFR 1507.3, DOE has consulted with CEQ regarding these final amendments to the DOE NEPA rule. CEQ has found that the amendments conform with NEPA and the CEQ regulations and has no objection to their promulgation.

II. Statement of Purpose

The amendments to the DOE NEPA regulations are intended to improve the efficiency of DOE's implementation of NEPA by clarifying and streamlining certain DOE requirements, thereby reducing implementation costs and time. This goal is consistent with the DOE Secretarial Policy Statement on NEPA (June 1994), which encourages actions to streamline the NEPA process without sacrificing quality and to make the process more useful to decision makers and the public. Full compliance with the letter and spirit of NEPA is an essential priority for DOE. In addition, DOE's missions, programs, and policies have evolved in response to changing national priorities since the current DOE NEPA regulations were issued in 1992, and DOE needs to make conforming changes in its NEPA regulations, e.g., to provide efficient NEPA procedures for waste management and property transfer actions, which are occurring with increasing frequency.

III. Comments Received and DOE's Responses

DOE has considered and evaluated the comments received during the public comment period. Many revisions suggested in these comments have been incorporated into the final amendments to the rule. The following discussion describes the comments received, provides DOE's responses to the comments, and describes any resulting changes to the proposed amendments. As a result of changes made in response to comments, several number designations of classes of actions have been changed in the final rule; section references, unless otherwise indicated, are to those in the proposed amendments.

Several commenters expressed overall support for DOE's efforts to increase efficiency and reduce NEPA compliance costs. One Federal agency (the Food and Drug Administration) and one state agency (the Virginia Department of Environmental Quality) stated that they had no objections to DOE's proposed amendments. No comments or only positive comments were received on the following proposed amendments to subpart D of the rule: Integral element B(1), B1.8, B1.18, B1.21, B1.31, B3.3, and D1. These proposed amendments, therefore, remain unchanged in the final rulemaking, and are not discussed further.

A. Procedural Comments

A few commenters addressed procedural aspects of this rulemaking. Specifically, one commenter stated that public Notice of Proposed Rulemaking was inadequate. DOE notes that the Notice of Proposed Rulemaking was published in the Federal Register on February 20, 1996. In addition, the Notice was mailed to more than 400 stakeholders and was made available for review and comment through the World Wide Web at DOE's NEPA Web Site. DOE believes that its effort to notify the public of its proposed rulemaking was sufficient.

In addition, two commenters requested that DOE hold public hearings on the proposed rulemaking at locations in close proximity to various DOE facilities and a reopening of the comment period until 90 days after publication of the schedule for public hearings. Other commenters also asked that the comment period be reopened.

In response, DOE reopened the comment period from April 19, 1996, through May 10, 1996. Further, as described in a separate Notice published elsewhere in this issue, DOE will again reopen the comment period, but only on the proposals to modify the typical classes of actions pertaining primarily to power marketing activities. DOE also held a public hearing in Washington, DC., on May 6, 1996, with accommodations for commenters who wished to present their views by conference telephone call from DOE regional offices throughout the United States.

DOE has fully considered all oral and written comments received through May 10, 1996. DOE believes that it has provided sufficient and appropriate public participation opportunities in its proposed rulemaking, and does not believe that additional hearings or an additional 90-day comment period on the entire proposed rulemaking is necessary.

Two commenters questioned the procedures DOE followed in determining that the proposed new and modified categorical exclusions would result in no significant impact, and indicated the need for documentation of this finding for each categorical exclusion in addition to the statement that appears in the preamble to the proposed rulemaking. In accordance with the CEQ regulations (40 CFR 1508.4), DOE initiated this rulemaking, in part, to define those classes of actions that DOE has found to have no significant effect on the human environment, either individually or cumulatively. DOE is not required by the CEQ regulations to set forth in the preamble a detailed, individualized explanation for its finding of no significant impact for each of the classes of actions in appendices A and B, but provides an overall finding in Section III.F, below.

One commenter requested that DOE prepare an environmental impact statement addressing the cumulative impacts of the proposed amendments. Two other commenters stated that an environmental assessment was necessary to determine whether the proposed amendments constituted a major Federal action.

DOE believes that its proposal to amend its NEPA implementing regulations falls within the categorical exclusion for procedural rulemaking (10 CFR part 1021, appendix A to subpart D, categorical exclusion A6). DOE's NEPA regulations prescribe the process under which the Department examines the environmental impacts of its proposed actions. The regulations do not set out substantive criteria for reaching a decision on a particular action, and thus are procedural only. For this reason, these amendments to the DOE NEPA regulations are properly excluded from NEPA documentation requirements. See also Section IV.A.

One commenter requested that DOE impose a moratorium on privatization pending completion of public hearings and an environmental impact statement on the proposed amendments. This request is outside the scope of this rulemaking, and DOE does not believe that the scope, which is restricted to DOE's proposed changes to 10 CFR part 1021, should be expanded. Any moratorium on privatization activities should be determined on the basis of the particular facts and circumstances and not in this rulemaking.

A commenter disagreed with DOE's statement in the preamble to the proposed rule that a review under the Unfunded Mandates Reform Act was not required because the DOE NEPA regulations affect only DOE. The commenter stated that many DOE facilities and actions have profound effects on other government agencies and the private sector. While DOE recognizes that its activities do affect other government agencies and the private sector, its regulations to implement the procedural provisions of NEPA impose obligations only on DOE, not on any state, local, or tribal government or on the private sector. Thus, further review by DOE under the Unfunded Mandates Reform Act is not required, and DOE is reiterating in this final rule its previous finding in the proposed rule. See Section IV.G.

B. General Comments on Proposed Amendments

Comments on Public Involvement Opportunities

Many commenters stated that the proposals regarding implementation plans, records of decision, and additions and modifications to the list of categorical exclusions would have the effect of reducing the public's knowledge of, and opportunities to participate in, DOE's decision making process. One commenter expressed concern that new and modified categorical exclusions would reduce the range of DOE actions subject to meaningful environmental review.

In proposing certain streamlining amendments to subpart C, DOE carefully weighed the benefits of improved efficiency against the acknowledged reduction in public information. DOE has reconsidered each such proposal in light of public comments and made some adjustments, as described below in Section III.D.

However, with regard to categorical exclusions, while the CEQ regulations encourage public participation in the NEPA process, they also direct agencies to use categorical exclusions (which, by definition, have no significant impact on the environment, either individually or cumulatively) to reduce paperwork (40 CFR 1500.4(p)) and delays (40 CFR 1500.5(k)). Consistent with this streamlining approach, the CEQ regulations do not provide for public participation in an agency's determination that a particular proposed action is categorically excluded.

DOE is amending its list of categorical exclusions by adding certain DOE classes of actions and modifying or clarifying other classes of actions currently on its list of categorical exclusions. In doing so, DOE has determined that these classes of actions do not have significant impacts on the environment, either individually or cumulatively. See Section III.F below. Thus, for these particular classes of actions, the environmental review that the commenter requested would not be meaningful in terms of evaluating significant impacts to the environment. DOE believes that it will serve environmental concerns and the public's interest best by focusing its efforts on the careful analysis of those actions that actually have the potential for significant impact.

DOE has considered comments on the merits of each proposed categorical exclusion amendment as discussed in Section III.F, but has decided generally to proceed with listing and modifying categorical exclusions, with the

knowledge that in some respects doing so would diminish opportunities for public involvement or information sharing.

Comments Outside the Scope of Proposed Rulemaking

DOE proposed changes to specific sections of its NEPA implementing procedures. DOE considers any comments received regarding the proposed changes to be within the scope of this rulemaking and has addressed such comments in this final rulemaking.

DOE received several comments that it considers to be outside the scope of this rulemaking. These include suggested modifications to provisions of the existing DOE NEPA regulations other than those DOE is proposing to modify or expand, suggestions for additional categorical exclusions, suggestions for broad changes to the DOE NEPA process, and comments on particular DOE proposed actions and DOE policies or procedures not related to DOE's NEPA regulations. Such comments are briefly discussed below.

Suggested Changes to Other Provisions of Existing DOE NEPA Regulations

Some commenters suggested changes to provisions of existing DOE NEPA regulations in addition to provisions that DOE proposed to modify or expand. These commenters sought changes to §§ 1021.216 (Procurement, financial assistance, and joint ventures), 1021.301 (Agency review and public participation), 1021.410 (Application of categorical exclusions (classes of actions that normally do not require EAs or EISs)), and B3.11 (Outdoor tests and experiments on materials and equipment components). While DOE is not considering such changes to its NEPA regulations at this time, DOE is taking these suggestions under advisement and may address them in a future rulemaking.

Suggestions for Additional Categorical Exclusions

A few commenters offered suggestions for additional categorical exclusions to cover facility deactivation activities; onsite transportation of packaged spent nuclear fuel or transuranic waste; onsite transportation of hazardous, mixed, and radioactive waste; relocation or reconfiguration of existing facilities, buildings, and operations within and between DOE sites; replacement of existing facilities in kind and in place; and treatment or disposal of hazardous waste at an existing offsite permitted facility. To the extent that these suggestions were not addressed in DOE's proposed additions and modifications to its list of typical classes of action, DOE considers them to be outside the scope of this rulemaking. DOE is taking these suggestions under advisement and may address them in a future rulemaking.

Suggested Changes to DOE's NEPA Process

Other commenters offered general suggestions for what they considered to be improvements to the DOE NEPA process; topics included the codification of DOE's enhanced public involvement procedures, improvement of DOE's notification procedures, the timing of NEPA actions, page limits for DOE environmental impact statements, coordination with state historic preservation officers, actions taken under consent orders, defining when the choice of reasonable alternatives becomes limited, use of ''worst case'' scenarios in NEPA documents, and delegation of decision making authority. One commenter requested that DOE ensure that its implementing rules and related policies, orders, and procedures are not applied unnecessarily to actions that are not ''major Federal actions.'' Although these comments are outside the scope of DOE's proposed rulemaking, DOE may consider these suggestions in a future rulemaking.

Comments Not Related to NEPA Regulations

A few commenters offered comments that are related to particular DOE proposed actions or other DOE policies and procedures. These include comments regarding whistleblower protection, privatization of DOE facilities, hearings on the Multi-Purpose Canister Environmental Impact Statement, management of spent nuclear fuel, cleanup of contaminated sites, Federal Acquisition Regulations, the Waste Management Programmatic Environmental Impact Statement, and contractor oversight. Because these comments relate to specific DOE actions and not to DOE's procedures for NEPA compliance, DOE finds these comments to be outside the scope of this rulemaking. Accordingly, they were not considered in developing the final rule.

Other Comments

One commenter stated that DOE should provide language in the rule that requires all DOE NEPA documents to substantiate compliance with all applicable environmental laws, Executive Orders, and other similar requirements. DOE notes that it must comply with all applicable environmental laws, Executive Orders, and similar requirements. With respect to the application of the categorical exclusions in appendix B to subpart D, DOE's NEPA regulations currently require that a proposed action must be one that would not ''[t]hreaten a violation of applicable statutory, regulatory, or permit requirements for environment, safety, and health'' in order to fit within a categorical exclusion (appendix B to subpart D, integral element B(1)).

One commenter objected to documenting the application of categorical exclusions to each and every activity that DOE undertakes; on the other hand, several commenters suggested the need for documentation to ensure that the integral elements (appendix B, B (1) through B(4) to subpart D of DOE's NEPA regulations) were properly considered and cumulative impacts would not result. DOE notes that neither the CEQ nor DOE NEPA regulations, nor DOE's internal NEPA procedures, require documenting the application of categorical exclusions (DOE Order 451.1, Section 5(d)(2)). The appropriate NEPA Compliance Officer is responsible for the proper application of categorical exclusions.

Another commenter stated that DOE should regularly prepare a list of the actions to which categorical exclusions were applied and make that list available to the public. DOE recognizes the value in informing the interested and affected public around DOE sites of its activities at those sites. However, a requirement for the periodic publication of a list of activities that have been categorically excluded would tend to undermine CEQ's strategy of using categorical exclusions to streamline the NEPA process.

One commenter stated that DOE's environmental review processes for compliance with NEPA and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) should be integrated. Another commenter expressed concern that the proposed amendments did not adequately address DOE's current policy on compliance with NEPA for CERCLA actions, as set forth in the Secretarial Policy Statement on NEPA (June 1994).

Under the current policy, DOE will rely on the CERCLA process for review of actions to be taken under CERCLA and will address NEPA values and public involvement procedures in its CERCLA processes to the extent practicable. DOE may choose, however, after consultation with stakeholders and as a matter of policy, to integrate the NEPA and CERCLA processes for specific proposed actions. The CERCLA/NEPA policy is applied on a case-by-

case basis, and DOE is satisfied that the new approach is clear and working adequately as a matter of policy that does not warrant codification in the regulations.

One commenter asked whether DOE should consider NEPA to be sufficiently specific and detailed to warrant the commitment to the ''letter'' of NEPA that DOE stated in its preamble to the proposed amendments. The commenter stated that such a commitment can create unnecessary concerns about the degree to which the responsibility for decision making can be delegated and justify unnecessarily restrictive and arbitrary decisions. While DOE agrees that the statute itself imposes few specific requirements, DOE believes that it is important to stress its commitment to complying with the express requirements, as well as with the intent of the statute to preserve, protect, and enhance the environment.

C. Comments on Amendments to Subpart A—General

Section 1021.105 Oversight of Agency NEPA Activities

One commenter expressed concern that the Office of NEPA Policy and Assistance was being eliminated and that the amendment proposed that oversight of DOE NEPA activities would be assumed by the Assistant Secretary for Environment, Safety and Health.

The oversight of DOE's NEPA activities has been and continues to be conducted by the Assistant Secretary for Environment, Safety and Health. On December 18, 1994, the office under the Assistant Secretary with specific responsibility for NEPA activities was renamed the Office of NEPA Policy and Assistance (formerly the Office of NEPA Oversight). The only modification to this section is a conforming change to incorporate the new name for the office.

D. Comments on Amendments to Subpart C—Implementing Procedures

Section 1021.312 EIS Implementation Plan

DOE received several comments supporting and several comments opposing the proposal to eliminate the requirement to prepare an implementation plan for every environmental impact statement.

Several commenters expressed concern that the public's opportunity for involvement would be reduced if an implementation plan were not prepared for every environmental impact statement. They stated that implementation plans provide an opportunity for the public to see how scoping comments will be addressed in the environmental impact statement, to formulate options and comments, to review contractor disclosure statements, and to keep the environmental impact statement on track. One commenter stated that the public has valuable insight to provide. Another commenter suggested that implementation plans are useful educational tools and an excellent introduction to the DOE NEPA process.

As discussed above in Section III.B, DOE weighed the benefits of improved efficiency from eliminating the implementation plan requirement against the acknowledged reduction in publicly available information. After considering all the comments received, DOE determined that because the public has the opportunity to provide comments on the scope of an environmental impact statement and can see how scoping comments were addressed and considered in the draft environmental impact statement, the value to the public and DOE of continuing the requirement for an implementation plan does not justify the cost, time, and resources required in preparing an implementation plan for every environmental impact statement.

With respect to contractor disclosure statements, DOE stated in the preamble to the proposed amendments that it would continue to prepare and require the execution of such statements by contractors, as required by 40 CFR 1506.5(c) of the CEQ regulations. In response to comments, however, DOE will include the contractor disclosure statements in draft and final environmental impact statements, and has modified 10 CFR 1021.310 accordingly.

One commenter stated that eliminating the implementation plan requirement will preclude requests from interested parties for environmental assessments and environmental impact statements before the agency proceeds with actions. Because an implementation plan is prepared after a decision has been made to prepare an environmental impact statement, and is not prepared at all for environmental assessments, DOE believes that eliminating the implementation plan requirement will not have any effect on the public's ability to request an environmental impact statement or an environmental assessment.

While some commenters supported eliminating the implementation plan requirement, they requested that notes from public scoping meetings be made available in public reading rooms or that DOE prepare a detailed administrative record of the disposition of public scoping comments and make it available to the public upon request. Another commenter, although supportive of the proposed amendment, suggested that DOE include a response to public scoping comments in the draft environmental impact statement.

DOE believes that the purpose in eliminating the implementation plan requirement (i.e., to achieve cost and time savings without meaningfully reducing public involvement in the DOE environmental impact statement process) would not be served by adopting the alternative suggestions (preparing a detailed administrative record or including a response to public scoping comments in a draft environmental impact statement) in place of the implementation plan requirement. The public scoping process under DOE's amended rule fully complies with the CEQ NEPA regulations, which require only that draft environmental impact statements be prepared in accordance with the scope decided upon in the scoping process (40 CFR 1502.9(a)).

One commenter stated that the environmental impact statement implementation plan should be optional. DOE agrees and intends for the elimination of the implementation plan requirement to have the effect of making such plans optional.

Finally, in its proposal to eliminate the requirement to prepare an implementation plan for an environmental impact statement, DOE inadvertently omitted making a corresponding change to § 1021.311(f), which included a reference to the EIS implementation plan. Section 1021.311(f) has now been removed from the final rule; paragraph (g) has been redesignated accordingly.

Section 1021.315 Records of Decision

Section 1021.315(c). Commenters opposed two aspects of this proposed amendment. First, some commenters expressed concern that DOE's proposal to allow publication in the Federal Register of a brief summary and notice of availability of a record of decision, rather than the full text, would shift to the public the cost of obtaining copies of a record of decision, and would not assure timely availability of the record of decision. Another commenter suggested that any savings achieved from not publishing the full text of a record of decision in the Federal Register would not be sufficient to justify the public's increased burden in seeking a record of decision. DOE has reconsidered the proposal in light of the commenters' concerns, and has decided that the cost-savings do not justify the burden associated with the proposed

change. Therefore, DOE will continue to publish the full text of records of decision in the Federal Register.

Second, commenters also expressed concern about the proposed clarification to § 1021.315(c) that, if a decision has been publicized by other means (e.g., press release or announcement in local media), DOE need not defer taking action until its record of decision has been published in the Federal Register. The commenters suggested that these other means of communication were not as reliable, accurate, easily available, or effective as the Federal Register.

This amendment is a clarification, not a substantive change, to DOE's regulations. Section 1021.315(b) currently states that ''No action shall be taken until the decision has been made public.'' One way to make a decision public is to publish the record of decision in the Federal Register, but decisions can be made public in other ways, such as through press releases or announcements in local media. DOE's proposed amendment merely clarifies the practice that DOE has followed previously under which DOE may proceed with an action after its decision has been made public but before that decision is published in the Federal Register. DOE needs to retain the ability to implement an action after making the record of decision public, but before publication of that decision in the Federal Register, in those instances when timing is critical.

One commenter questioned whether DOE was proposing to implement an action before the decision is articulated in writing and signed. DOE is not making such a proposal. To clarify this point, DOE has modified the final language in a new § 1021.315(d) by indicating that DOE may implement a decision if the record of decision has been signed and the decision and the availability of the record of decision have been made public.

Another commenter indicated confusion over DOE's proposal to modify § 1021.315(c) rather than § 1021.315(b). In response, and to provide further clarification, DOE has moved the second sentence from current § 1021.315(b) to begin a new § 1021.315(d), and added to the new subsection (d) the language previously proposed for § 1021.315(c), as modified above. Section 1021.315(c) remains as in the current regulation, and current § 1021.315(d) is now § 1021.315(e). Pertinent sections of § 1021.315 are now changed as follows:

(a) (no change)

(b) If DOE decides to take action on a proposal covered by an EIS, a ROD shall be prepared as provided at 40 CFR 1505.2 (except as provided at 40 CFR 1506.1 and § 1021.211 of this part).

(c) (no change)

(d) No action shall be taken until the decision has been made public. DOE may implement the decision before the ROD is published in the Federal Register if the ROD has been signed and the decision and the availability of the ROD have been made public by other means (e.g., press release, announcement in local media).

(e) DOE may revise a ROD at any time, so long as the revised decision is adequately supported by an existing EIS. A revised ROD is subject to the provisions of paragraphs (b), (c), and (d) of this section.

Section 1021.322 Findings of No Significant Impact

Section 1021.322(b)(1). Under the proposed amendment, and in accordance with 40 CFR 1508.13, DOE would either incorporate the environmental assessment by reference in a finding of no significant impact and attach the environmental assessment, or summarize the environmental assessment in the finding. A few commenters supported the proposal to remove the requirement to summarize the environmental assessment in the finding of no significant impact in all cases. Others expressed concern that DOE was proposing to eliminate information that is currently being provided to the public.

This proposal is intended to eliminate redundancy by requiring either the attachment of an environmental assessment to the related finding of no significant impact or the inclusion of a summary of an environmental assessment in the related finding of no significant impact, but not both. This would change DOE's current practice of summarizing the environmental assessment in each finding of no significant impact and also attaching the environmental assessment to the finding of no significant impact. For a finding of no significant impact published in the Federal Register, it would be necessary to summarize the environmental assessment in the finding of no significant impact, because the environmental assessment would not be published in the Federal Register.

E. General Comments on Subpart D—Typical Classes of Actions

Many of the commenters suggested, both generally and with regard to specific proposed amendments to classes of actions in subpart D, that DOE's terminology was too vague or subjective to adequately define classes of actions. For example, commenters objected to DOE's use of such terms as ''small-scale,'' ''short-term,'' ''minor,'' and ''generally,'' among others, as being too imprecise. On the other hand, where DOE had proposed using specific quantities to aid in defining a class of actions (e.g., 50,000 square feet of area and 100 MeV (million electron-volts) of energy), commenters asked why DOE had picked the proposed value rather than any other, and how DOE could justify such apparent precision.

DOE has considered all such comments in the context of the individual proposed amendments to subpart D classes of actions presented in Section III.F, below. To provide additional information and to simplify the more specific discussions, DOE is providing the following general response.

DOE formulates subpart D classes of actions based on DOE's experience, other agencies' experience as reflected in their NEPA procedures, technical judgments regarding impacts from actions, and public comments on a proposed rule. To minimize subjectivity in interpretation, DOE uses both numerical values of quantities (which have clear meaning) and descriptive words such as ''minor'' and ''small-scale,'' which suggest the smaller actions in a class, not the larger. DOE also uses examples, both to clarify that the class of actions includes the specific examples cited, and to suggest the nature of actions that may be included.

With regard to DOE's use of specific quantities in several of the proposed classes of actions, commenters had two general objections. First, they noted correctly that using ''generally'' in defining a class of actions (e.g., proposed B1.26 and B3.10) could allow the class to be applied to proposed actions that would otherwise not even approximately fit the definition. Second, commenters questioned the justification for the specific quantity values chosen and even whether any specific value could be justified.

DOE's intention with respect to both issues is better expressed by the concept of ''approximately'' rather than ''generally,'' and the classes of actions in the final rule have been changed accordingly. By using ''approximately,'' DOE is indicating that the numerical values used in defining classes of actions are to be interpreted flexibly rather than with unwarranted precision. For example, DOE proposed to categorically exclude construction of small accelerators and decided that it could express the class of actions as including accelerators less than 100 MeV in energy. DOE acknowledges that judgment is involved and that it could

have chosen numbers somewhat greater than 100 MeV to limit the categorical exclusion. DOE believes, however, that the phrase ''less than approximately 100 MeV in energy'' provides appropriate flexibility and represents the best overall resolution of the matter.

One commenter expressed concern that DOE had not taken the opportunity to decrease the level of prescription and detail in the DOE NEPA regulations. The commenter expressed particular concern that DOE had proposed 17 new classes of actions, many of which the commenter believed would add little or no value to DOE's NEPA process. Similarly, another commenter stated that DOE should make existing categorical exclusions more comprehensive whenever possible, rather than simply expand the list of categorical exclusions.

In proposing amendments to the DOE NEPA rule, DOE considered making the list of categorical exclusions shorter by combining certain actions and making the list more comprehensive by broadening the categories. DOE declined to pursue such a course of action generally in this rulemaking, although it proposed to combine two classes of actions. DOE's extensive list of categorical exclusions results primarily from the fact that DOE is engaged in many different types of activities.

One commenter requested that DOE define the phrase ''already developed area'' that is used in several proposed new or amended categorical exclusions (e.g., B1.15, B1.22, B3.6, B3.10, B3.12, and B6.4). The commenter expressed concern that DOE may consider portions of wildlife management areas surrounding DOE facilities to be ''developed'' merely because of DOE ownership or because of the existence of abandoned DOE facilities. In the existing and proposed regulations, DOE used the parenthetical phrase ''where site utilities and roads are available'' to help define ''an already developed area'' in the classes of actions in the final rule. For further clarity, DOE has modified the parenthetical phrase to read ''where active utilities and currently used roads are readily accessible.'' DOE does not intend to include wildlife areas and abandoned facilities in its definition of ''an already developed area.''

Finally, several commenters noted that DOE defined categorical exclusions as classes of actions that ''normally'' do not require environmental assessments or environmental impact statements. One of these commenters suggested that ''normally'' should mean 99 percent of the time, and this commenter and others stated that there should be provisions for extraordinary circumstances under which a proposed action listed in appendices A or B should not be categorically excluded.

DOE's use of the term ''normally'' in the context of categorical exclusions is consistent with the use of this term in the CEQ regulations, which state that an agency's NEPA implementing procedures for categorical exclusions ''shall provide for extraordinary circumstances in which a normally excluded action may have a significant environmental effect'' (40 CFR 1508.4). See also 40 CFR 1507.3(b)(2)(ii), in which CEQ directs agencies to identify classes of actions ''which normally do not require either an environmental impact statement or an environmental assessment.'' DOE believes that its categorical exclusions comply with CEQ's regulations, i.e., to be eligible for categorical exclusion, a class of actions must not have significant effects on the human environment except in extraordinary circumstances that may affect the significance of the environmental effects of a specific proposed action. DOE's existing regulations (10 CFR 1021.410(b)(2)) describe the nature of extraordinary circumstances under which a categorical exclusion should not be applied, and explicitly require (§ 1021.400(d)) an environmental assessment or environmental impact statement for a proposed action that presents such circumstances. Therefore, DOE does not believe any changes are needed to address the use or interpretation of the word ''normally'' in DOE's description of categorical exclusions or the manner in which DOE provides for extraordinary circumstances.

F. Comments on Appendices of Subpart D—Typical Classes of Actions

Several commenters objected to many categorical exclusions on the grounds of cumulative effects, connected actions, or extraordinary circumstances, but without explanation as to their specific objection. A categorical exclusion is a class of actions that, individually or cumulatively, do not have significant environmental impacts. If there are extraordinary circumstances associated with a proposed action, or if the proposal is connected to other actions with potentially significant impacts or related to other proposed actions with cumulatively significant impacts, then a categorical exclusion would not apply under § 1021.410(b).

Another commenter noted that several of the proposed categorical exclusions referred to ''siting, construction, operation, and decommissioning'' of various DOE activities and questioned whether such activities would also need state permits. DOE notes that while new construction could require state or local permits, one of the integral elements for all appendix B categorical exclusions is that the proposed action ''does not threaten a violation of applicable statutory, regulatory, or permit requirements for environment, safety, and health.'' Any DOE action would be required to comply with applicable state and local requirements, independent of the level of NEPA review appropriate under DOE's NEPA regulations.

In general, the following responses to comments regarding specific categorical exclusions should be read in the full context of the DOE regulations for categorical exclusions. Under the current regulations, before a proposed action may be categorically excluded, DOE must determine in accordance with § 1021.410(b) that (1) the proposed action fits within a class of actions listed in appendix A or B to subpart D, (2) there are no extraordinary circumstances related to the proposal that may affect the significance of the environmental effects of the action, and (3) there are no connected or related actions with cumulatively significant impacts and, where appropriate, the proposed action is a permissible interim action. In addition, to fit within a class of actions that is normally categorically excluded under appendix B, a proposed action must include certain integral elements (appendix B, paragraphs B (1) through (4)). These conditions ensure that an excluded action will not threaten a violation of applicable requirements, require siting and construction of waste management facilities, disturb hazardous substances such that there would be uncontrolled or unpermitted releases, or adversely affect environmentally sensitive resources.

The headings below are those used in the table of contents of the appendices in the proposed amendments. The conversion table below shows which classes of actions have been included in the final amendments to the rule. There were a few numbering changes between the proposed and final amendments because some classes of actions were added or removed. Specifically, the proposed B1.32 was removed, and the proposed B1.33 was renumbered as B1.32; existing B6.4, which had been proposed for revision, was retained without change, and a new B6.10 was added to incorporate some of the changes proposed for B6.4; and the proposed modification to C9 was withdrawn. These changes are explained more fully in the following discussion.

CONVERSION TABLE

Existing rule	Final amendments	
A.7	A.7	Clarified.
B(1)	B(1)	Modified.
B(2)	B(2)	Do.
B1.3	B1.3	Clarified.
B1.8	B1.8	Modified.
B1.13	B1.13	Do.
B1.15	B1.15	Do.
B1.18	B1.18	Do.
B1.21	B1.21	Do.
B1.22	B1.22 & B1.23	Clarified.
	B1.24—B1.32	Added.
	B2.6	Do.
B3.1	B3.1	Clarified.
B3.3	B3.3	Do.
B3.6	B3.6	Modified.
B3.10	B3.6	Do.
	B3.10	Added.
	B3.12–B3.13	Do.
B5.3	B5.3	Modified.
B5.5	B5.5	Do.
B5.9–B5.11	B5.9–B5.11	Clarified.
B5.12–B5.16	Removed.	
	B5.12	Added.
B6.1	B6.1	Modified.
B6.5	B6.5	Clarified.
	B6.9–B6.10	Added.
C1	C1	Reserved.
C10	C10	Do.
C11	C11	Modified.
C14	C14	Do.
C16	C16	Do.
D1	D1	Do.
D10	D10	Do.

Finally, after considering all public comments on the proposed amendments, DOE has determined that the final amendments to appendices A and B constitute classes of actions that do not individually or cumulatively have a significant effect on the human environment, and are covered by a finding to that effect in § 1021.410(a). In making this finding, DOE has considered, among other things, its own experience with these classes of actions, other agencies' experience as reflected in their NEPA procedures, DOE's technical judgment, and the comments received on the proposed amendments.

- Proposed Clarification A7 Transfer of property, use unchanged.

One commenter stated that DOE cannot assume that transfer of property will not result in short- and long-term changes in impacts. DOE proposed to amend paragraph A7 only to clarify the meaning of property by explicitly including both personal property (e.g., equipment and material) and real property (e.g., permanent structures and land). DOE did not propose to amend the requirement regarding property use remaining unchanged. The categorical exclusion may only be applied when the impacts would remain essentially the same after the transfer as before. See also the discussion of B1.24 and B1.25.

Classes of Actions Listed in Appendix B

- Proposed Modification to Integral Element B(2).

DOE proposed to modify integral element B(2)—which sets the condition that a categorically excluded action may not require siting, construction, or major expansion of waste storage, disposal, recovery, or treatment facilities—to provide an exception for such actions that are themselves categorically excluded. DOE proposed this change to conform to simultaneously proposed changes (B1.26, B1.29, B6.4, and B6.9) that would categorically exclude certain water treatment and waste storage facilities.

Two commenters objected to the change, apparently as an extension of their objections to the proposed categorical exclusion amendments that prompted DOE's proposal to modify B(2). Another commenter expressed concern that the proposed B(2) would imply that ''major'' expansion of waste facilities might be categorically excluded. This interpretation was unintended and the language has been modified. In other respects, however, DOE has retained the B(2) amendment as necessary to conform to certain final categorical exclusions (B1.26, B1.29, B6.9, and B6.10). As finally revised, B(2) reads as follows: ''To fit within the classes of actions (in appendix B), a proposal must be one that would not . . . require siting and construction or major expansion of waste storage, disposal, recovery, or treatment facilities (including incinerators), but the proposal may include categorically excluded waste storage, disposal, recovery, or treatment actions.''

- Proposed Modification to Integral Element B(4)(iii).

DOE intended to modify this integral element to allow the categorical exclusion of actions listed in appendix B despite their having an adverse impact on small, low quality wetlands. DOE anticipated that activities in such areas would not have a significant environmental impact, either individually or cumulatively. While several commenters supported the proposed change, others expressed concern about the potential cumulative impacts, the institution of a threshold size, the meaning of ''covered'' by a general permit, and the difference between a ''general'' permit and a ''Nationwide'' permit.

In consideration of the comments and after consultation with staff of the U.S. Army Corps of Engineers (Corps), DOE has revised B(4)(iii) to allow the categorical exclusion of actions in wetland areas not considered waters of the United States and thus not regulated under the Clean Water Act. This includes certain drainage and irrigation ditches, artificial lakes and ponds, and borrow pits, as discussed below.

The Corps generally does not consider the following areas to be waters of the United States: (a) Non-tidal drainage and irrigation ditches excavated on dry land; (b) artificially irrigated areas which would revert to upland if the irrigation ceased (for DOE this would include areas ''irrigated'' by leaking pipes, tanks, or ditches); (c) artificial lakes or ponds created by excavating and/or diking dry land to collect and retain water and which are used exclusively for such purposes as stock watering, irrigation, settling basins, or rice growing; (d) artificial reflecting or swimming pools or other small ornamental bodies of water created by excavating and/or diking dry land to retain water for primarily aesthetic reasons; (e) waterfilled depressions created in dry land incidental to construction activity and pits excavated in dry land for the purpose of obtaining fill, sand, or gravel unless and until the construction or excavation operation is abandoned and the resulting body of water meets the definition of waters of the United States under 33 CFR 328.3(a). See 51 FR 41206, 41217 (November 13, 1986). The Corps reserves the right, however, on a case-by-case basis to determine that a particular water body within these categories fits within the definition of waters of the United States. The U.S. Environmental Protection Agency (EPA) also has the right to determine on a case-by-case basis if any of these areas are waters of the United States. Note that some of these areas could become waters of the United States and subject to regulation. This may occur if the area no longer meets the above criteria, e.g., the area is no longer used for the purpose for which it was constructed or is abandoned. In such cases, a categorical exclusion could not be applied.

The wording of B(4)(iii) has been modified from the proposed rule as follows: ''Wetlands regulated under the Clean Water Act (33 USC 1344) and floodplains.''

- Proposed Clarification B1.3 Routine maintenance/custodial services for buildings, structures, infrastructures, equipment.

One commenter asked for clarification of ''in kind replacement.'' The commenter stated that, with regard to older facilities, certain equipment used in the facilities is no longer made or its installation at this time would be

contrary to code or good management practices. The commenter asked if replacing equipment in older facilities with modern components is considered ''in kind replacement.''

DOE recognizes that the equipment used in many of its facilities cannot be replaced literally ''in kind'' for the reasons the commenter states. DOE believes, however, that the description of ''in kind replacement'' presented in the proposed clarification for B1.3 (i.e., in kind replacement includes installation of new components to replace outmoded components if the replacement does not result in a significant change in the expected useful life, design capacity, or function of the facility) adequately addresses the commenter's request.

B1.3(n). One commenter suggested that instead of adding additional examples of testing and calibration of facility components to B1.3, that the word ''maintenance'' be added to B3.1. DOE has chosen to address routine maintenance under a separate categorical exclusion rather than adding it to other categorical exclusions where it might apply.

B1.3(o). One commenter thought that the term ''routine decontamination'' needed additional clarification. DOE uses ''routine'' to mean a recurring action that is done easily and is well understood, such as wiping with rags, using strippable latex, and minor vacuuming. B1.3(o) is intended to categorically exclude contamination-cleanup activities of a routine nature.

- Proposed Modification B1.13 Construction/acquisition/relocation of onsite pathways, spur or access roads/ railroads.

DOE proposed to expand existing B1.13 (Acquisition or minor relocation of existing access roads serving existing facilities if the traffic they are to carry will not change substantially) by adding construction and spur roads, pathways and railroads, and by deleting the phrase ''serving existing facilities if the traffic they will carry will not change substantially.'' One commenter questioned the definition of ''spur'' and ''access'' roads. Another commenter suggested more restrictive language for B1.13 so that it would be applied only in instances to improve safety, and only if the total traffic volume would not substantially change. A third commenter expressed concern that applying the categorical exclusion could eliminate valuable input from natural resource agencies and cause potential significant impacts to wildlife, including loss of habitat, habitat fragmentation, and degradation of adjacent habitat. Another commenter stated that the actions proposed to be categorically excluded should be subject to public review.

In response to the concerns raised by these commenters, DOE has made two changes to the proposed modification to B1.13. First, DOE has deleted the reference to ''spur roads'' because the term ''access roads'' adequately encompasses the intended purpose. Second, DOE has revised the categorical exclusion to apply only to the construction of ''short'' access roads and access railroads. DOE acknowledges that the construction of onsite access roads could result in adverse environmental impacts. DOE believes, however, that the general restrictions on the application of categorical exclusions, particularly at § 1021.410 and the integral elements at appendix B, B(1)–B(4), will provide adequate safeguards to ensure that this class of actions is not applied to activities that could result in significant effects. Also, it is DOE's intention that the inclusion of the term ''short'' will further clarify the length of access roads and railroads that DOE intended to be constructed under this categorical exclusion (i.e., no more than a few miles in length). The categorical exclusion B1.13 now reads: ''Construction, acquisition, and relocation of onsite pathways and short onsite access roads and railroads.'' DOE does not believe that actions qualifying under this categorical exclusion warrant public review. See Section III.B, above.

- Proposed Modification B1.15 Siting/construction/operation of support buildings/support structures.

One commenter suggested that the categorical exclusion be expanded to include deactivation and demolition of the same structures. Such expansion is not necessary because these activities are included under proposed categorical exclusion B1.23.

Two commenters suggested that the phrase ''but not limited to'' be inserted between ''including'' and ''prefabricated buildings and trailers.'' DOE has incorporated the suggestion, as well as reversing the order of ''prefabricated buildings'' and ''trailers,'' to be consistent with B1.22.

One commenter stated that actions covered by this categorical exclusion should be subject to public review. For the reasons stated in Section III.B, DOE believes that public review is not appropriate.

One commenter asked for a definition of an ''already developed area,'' a phrase used in the existing regulations. The phrase in the proposed B1.15, ''where site utilities and roads are available,'' was intended to define the term. For clarification, DOE has modified this phrase to read ''where active utilities and currently used roads are readily accessible.'' See the discussion of ''already developed area'' in Section III.E.

- Proposed Clarification B1.23 Demolition/disposal of buildings.

DOE proposed to divide the existing categorical exclusion B1.22 into two categorical exclusions to clarify that the two actions included in the existing class of actions—relocation of buildings (proposed B1.22) and demolition and subsequent disposal of buildings, equipment, and support structures (proposed B1.23)—are not connected actions (i.e., actions that are closely related and therefore needed to be considered in the same NEPA review).

DOE received three comments on B1.23, none of which directly related to the proposed clarification. One commenter suggested that the categorical exclusion should be applicable to contaminated buildings that, after demolition, could be entombed in place. Another commenter questioned whether DOE was mandating disposal of construction debris in landfills. Apparently, this commenter's concern is based on DOE's intended clarification that building relocation actions are separate from building demolition and disposal. In any event, DOE is not mandating the disposal of construction debris in landfills. The third commenter objected to the categorical exclusion on the grounds of cumulative effects, connected actions, or extraordinary circumstances. DOE has responded to this objection, which was also expressed by other commenters in regard to other categorical exclusions, in Section III.F.

DOE does not intend for proposed categorical exclusion B1.23 to apply to in-place entombment of demolished structures. However, this categorical exclusion could be applied to the demolition and disposal of contaminated structures if releases are controlled or permitted and other conditions for application of the categorical exclusion are met.

- Proposed B1.24 Transfer of property/residential, commercial, industrial use; and
- Proposed B1.25 Transfer of property/habitat preservation, wildlife management.

DOE received several comments on these two proposed categorical exclusions. One commenter, noting that proposed B1.24 and B1.25 were similar, suggested combining them. Based on this comment and other comments that expressed concern about the broad scope of the categorical exclusions as proposed, DOE has retained both

categorical exclusions, but changed their wording to clarify DOE's intentions for their scopes and the differences between them. Categorical exclusion B1.24 as now revised refers to transfer, lease, disposition, or acquisition of interests in structures and equipment, and only land that is necessary for use of the transferred structures and equipment. Proposed B1.25 as revised refers to transfer of interests in land for purposes of habitat preservation or wildlife management, and only buildings that support those purposes.

One commenter questioned the meaning of ''uncontaminated.'' DOE has added a definition to each of these two proposed categorical exclusions that states that ''uncontaminated means that there would be no potential for release of substances at a level, or in a form, that would pose a threat to public health or the environment.'' This definition is based on the definition of contaminant in CERCLA § 101(33). DOE already has defined ''contaminant'' in § 1021.104 of its existing NEPA regulations as ''a substance identified within the definition of contaminant in Section 101(33) of CERCLA (42 USC 9601.101(33)).''

Several commenters questioned the feasibility of making a determination about potential releases and impacts that could occur after the transfer, as required by the categorical exclusions, without some formal environmental analysis (e.g., an environmental assessment). With regard to proposed B1.24, one of the commenters questioned how DOE would know if contaminant releases increase after transfer, stating that private operators, unlike DOE, are under no obligation to provide records of types, volumes, and pathways of contaminants released into the environment. In applying these two categorical exclusions (as in applying any other categorical exclusion), DOE will consider reasonably foreseeable circumstances, but will not attempt to speculate on all possible circumstances that the future could present. DOE believes that it will be able to determine whether a proposed post-transfer use is similar enough to the existing use to meet the conditions of the categorical exclusion, i.e., no decrease in environmental quality, no increased discharges, and generally similar environmental impacts. If DOE cannot make these judgments without environmental analysis, DOE will prepare at least an environmental assessment.

One commenter stated that the proposed categorical exclusion B1.24 was a positive step, but thought DOE had unduly limited its application. Another commenter stated that proposed categorical exclusion B1.24 was an improvement in that property transfers that could be categorically excluded would not be limited to those where use remains the same. This commenter wanted to expand the proposed categorical exclusion B1.24 to include transfers to other Federal agencies without restrictions on environmental parameters, because other Federal agencies must conduct their own NEPA review for future uses of the property. DOE believes that it must conduct the proper level of NEPA review for its actions, and that a NEPA review for the transfer, lease, disposition, or acquisition of property must consider reasonably foreseeable uses and conditions of those uses, regardless of whether the transfer would be to another Federal agency.

Two commenters expressed concern about eliminating community involvement in DOE's decisions about future land use. One commenter stated that the transfer of potentially contaminated land without environmental analysis would be inconsistent with DOE's openness policy. DOE does not intend to categorically exclude the transfer of contaminated property. However, DOE recognizes that in listing these classes of actions as categorical exclusions, the sharing of public information will be diminished in some instances, as discussed in Section III.B.

One commenter questioned whether categorical exclusion B1.24 would apply to a facility that had been idle (and thus not discharging any pollutants into the environment), allowing the facility to resume operations and resulting in pollutant discharges. If the facility to be transferred has not been in operation and transfer of the facility would result in the resumption of operation, then greater environmental discharges would result, making this proposed activity ineligible for this categorical exclusion.

With regard to proposed B1.25, one commenter suggested that the preamble was unclear because the categorical exclusion deals with the transfer, lease, and disposition of habitat lands and not a change to the habitat. The commenter also stated that a habitat improvement that supported the existing species of plants and animals, although a change, would not have the potential for significant impact and therefore could be categorically excluded.

There are three categorical exclusions related to the transfer of property: A7, where the use will remain the same; B1.24, where the use may change but the environmental impacts are similar; and B1.25, where the use will be habitat preservation or wildlife management. Small-scale improvements to fish and wildlife habitat are included under existing categorical exclusion B1.20. A large-scale habitat improvement project may have significant environmental effects, albeit beneficial, and would not be categorically excluded.

A commenter suggested that DOE should not assume that significant environmental and socioeconomic impacts will not result from the transfer of uncontaminated lands for habitat preservation and wildlife management, because DOE cannot reasonably predict the types of uses that private interests, conservation groups, or local and state agencies might allow for these lands. DOE agrees that it cannot project with certainty all future activities that might be allowed on any land that it transfers, leases, or disposes. However, categorical exclusion B1.25 is intended for application in those cases where the circumstances of the property transaction create a reasonable expectation that the property will be used for habitat preservation and wildlife management for the reasonably foreseeable future.

- Proposed B1.26 Siting/construction/operation/decommissioning of small water treatment facilities, generally less than 250,000 gallons per day capacity.

Several commenters recommended that DOE not categorically exclude water treatment facilities that would involve highly toxic substances, regardless of the limited rate at which water could be processed. Some commenters stated that the 250,000 gallon criterion was not necessarily the relevant factor regarding environmental impacts. The commenters also expressed concern that cumulatively significant effects would occur from repeated applications of this proposed categorical exclusion. DOE believes that the adverse environmental effects of concern to many of the commenters are highly unlikely. DOE chose to categorically exclude treatment facilities with less than about 250,000 gallons capacity because such small plants have little potential for significant impacts, especially in light of the safeguards afforded by the integral elements. For example, a DOE categorical exclusion may not be applied where the proposed action could adversely affect an environmentally sensitive resource (10 CFR part 1021, subpart D, appendix B, B(4)). Regarding cumulative effects, appendix B listings are not applicable to a proposed action that is connected to other actions with potentially significant impacts or related to other

proposed actions with cumulatively significant impacts (10 CFR 1021.410(b)(3)). Nevertheless, DOE has modified the proposal as one commenter suggested, so that, in addition to small potable water and sewer facilities, only those small wastewater and surface water treatment facilities whose liquid discharges are subject to external regulation would be categorically excluded. See also the discussion regarding the use of the word ''generally'' and numerical values in Section III.B.

• Proposed B1.27 Facility deactivation.

One commenter expressed concern that the categorical exclusion would apply to any facility and that deactivation is not clearly defined. The commenter suggested that if DOE intended the categorical exclusion to apply only to the disconnection of utilities, then it should be rewritten as: ''The disconnection of utilities such as water, steam, telecommunications, and electrical power after it has been determined that the continued operation of these systems is not needed for safety.'' DOE agrees and has rewritten the categorical exclusion as suggested. The term deactivation is no longer included in the categorical exclusion.

Another commenter suggested that the categorical exclusion be clarified to include provisions for partial disconnections and utility modifications where equipment may be required to remain operational at a reduced level. DOE believes that this categorical exclusion encompasses such disconnections and modifications.

One commenter stated that the risk posed by surplus facilities varies greatly and that DOE should be cautious in presuming NEPA documentation is not required. DOE agrees that the risks posed by particular facilities can vary, but believes that merely disconnecting the utilities of such facilities will not cause significant environmental impacts.

Another commenter questioned whether DOE intended to deactivate nuclear electrical utility facilities under this categorical exclusion, and suggested that such activities would require consultation and cooperation with other state and federal agencies and full public notice and participation. The proposed categorical exclusion would apply only to DOE facilities and not to the commercial nuclear power industry or other commercial powerplants.

• Proposed B1.28 Minor activities to place a facility in an environmentally safe condition, no proposed uses.

Several commenters questioned the scope of the categorical exclusion and generally expressed concern with the use of the word ''minor.'' Several commenters suggested that DOE more narrowly define what it intended to cover in this categorical exclusion (e.g., the meaning of ''adequate treatment, storage, or disposal facilities'' and ''no proposed use''). Other commenters stated that such activities could be carried out on a large scale at a particular site and that there could be cumulative impacts associated with waste management activities.

As discussed in Section III.E, DOE believes that the word ''minor'' is useful in describing the types of activities contemplated by the categorical exclusion, particularly when combined with examples and exclusions. DOE intends this categorical exclusion to apply to activities needed to place a surplus facility (one that will no longer be used by DOE for any purpose, including storage) in an environmentally safe condition, where there are existing treatment, storage, or disposal facilities with existing capacity to manage the resulting waste (including low-level radioactive waste). These activities include the final defueling of a reactor, as stated in the example in the proposed rule. DOE emphasizes that this categorical exclusion, like all other categorical exclusions, may not be applied in situations involving extraordinary circumstances (such as uncertain effects or effects involving unique or unknown risks) or where the proposal is connected to other actions with potentially significant impacts (see § 1021.410(b) (2) and (3)). Thus, if a proposal involved a mode of decontamination with potentially significant environmental effects or if it posed serious potential risks to workers, the public, or the environment, then the proposed activity would not be eligible for a categorical exclusion. DOE believes that the language of the proposed categorical exclusion, together with the general restrictions on the application of categorical exclusions, particularly at § 1021.410 and the integral elements at appendix B, B(1)–B(4), provide adequate safeguards to ensure that this categorical exclusion is not applied to activities that could result in significant environmental effects.

One commenter asked that the relationship of this categorical exclusion to CERCLA and the Resource Conservation and Recovery Act (RCRA) procedures be clarified. DOE's CERCLA/NEPA policy is discussed in Section III.B. Although DOE's RCRA procedures are outside the scope of this rulemaking, DOE notes that its application of this categorical exclusion would have no effect on its compliance with RCRA.

Another commenter recommended that the categorical exclusion be broadened to include removal of contaminated equipment, material, and waste and include activities such as size reduction and placement of wastes in storage containers if done in the same building. DOE intends the categorical exclusion, as proposed, to include these activities.

• Proposed B1.29 Siting/construction/operation/decommissioning of onsite disposal facility for construction and demolition waste.

Several commenters objected to this categorical exclusion. One commenter expressed concern that new disposal facilities for construction and demolition waste could be sited and constructed in environmentally sensitive areas, such as priority shrub steppe habitat, with adverse impacts on wildlife. This commenter also expressed concern about cumulative impacts from multiple facilities. DOE believes that integral element B(4), which states that an action proposed for categorical exclusion must not adversely affect environmentally sensitive areas, would preclude use of the proposed categorical exclusion for construction of disposal facilities in priority shrub steppe habitat. Also, under § 1021.410(b)(3) of its NEPA implementing regulations, DOE may not categorically exclude a proposed action that may be connected to other actions with potentially significant impacts, or related to other proposed actions with cumulatively significant impacts.

Another commenter expressed concern that a 10-acre disposal facility could pose major health and safety risks to workers and members of the public in adjacent communities, noting in particular the potential for adverse impacts on air quality. By limiting this categorical exclusion to disposal of uncontaminated materials, DOE believes there would be no harmful releases of contaminants and no increased health impact to workers or the nearby public. DOE has revised the language in this categorical exclusion in the final amendments by inserting the phrase ''which would not release substances at a level, or in a form, that would pose a threat to public health or the environment'' to explain the term ''uncontaminated.'' This new language corresponds to the definition of ''contaminant'' in DOE's NEPA regulations, which in turn is based on CERCLA § 101(33). In addition, DOE employs standard industrial practices, such as water spraying to control dust, in operating any of its facilities, and DOE believes that any particulate

emissions would be adequately controlled to protect workers and the public. To correspond to other changes in the final amendments, DOE has changed the phrase ''generally less than 10 acres in area,'' to ''less than approximately 10 acres.'' See also the discussion in Section III.E.

Another commenter stated that the scope of the categorical exclusion was so broad that the host community, state and local officials, and interested citizens could be excluded from participating in decisions that may have significant environmental and socioeconomic impacts. DOE believes that this class of actions normally does not have potential for significant impacts and has decided to list it as a categorical exclusion in the final amendments. See also the discussion of public involvement and information sharing opportunities in Section III.B.

One commenter requested that the proposed categorical exclusion be expanded to include on-site disposal facilities for all uncontaminated waste, including office and cafeteria waste. This comment is outside the scope of this rulemaking, but DOE may consider the suggestion in a future rulemaking.

• Proposed B1.30 Transfer actions.

Several commenters objected to this proposed categorical exclusion as too broad and open ended, some noting potential for adverse impacts. Some commenters requested that it be deleted; others requested that limits be provided on the quantity and types of materials and wastes that could be transported. Other commenters sought additional clarification.

In contrast, two commenters stated that the proposed categorical exclusion was too limited in scope and suggested broadening the categorical exclusion to include routine transportation of materials, equipment, and wastes that are managed in accordance with regulatory requirements. One of these commenters noted DOE's statement in the preamble to the proposed rulemaking that ''transportation activities under DOE's standard practices pose no potential for significant impacts.''

All DOE proposed actions must comply with applicable regulatory requirements, although some actions nevertheless may have significant impacts. DOE will continue to include analysis of transportation impacts in environmental assessments and environmental impact statements where the scope of the proposed actions presents potential for significant impact.

DOE has revised the language of the categorical exclusion to characterize the amount of materials, equipment, or waste to be transferred as ''small'' in addition to being incidental to the amount at the receiving site. This revision addresses the concerns expressed by several commenters that DOE had proposed to limit the amount of material or waste that could be transported, not by the impacts that might occur by transport of the material or waste, but by the amount of material or waste at the receiving site.

One of these commenters stated that the proposed categorical exclusion could be applied to the transport of thousands of containers of materials or waste to a site that had yet larger amounts. Another commenter stated that the baseline for determining the amount of waste or material that could be received at a site, under the proposed categorical exclusion, would continually increase as waste or materials were transferred to the site. The revision reinforces DOE's intention that use of the categorical exclusion should not add significantly to what may already be significant amounts of waste or materials at a site.

Several commenters stated that transportation of radioactive materials and waste is likely to be a key or controversial issue to local communities. One commenter stated that unscheduled transportation of waste would generate considerable community interest, and another expressed concern that the host community, state and local officials, and interested citizens could be excluded from participating in decisions that may result in significant environmental and socioeconomic impacts. DOE believes that this class of actions normally does not have potential for significant impacts and has decided to list it, as revised, as a categorical exclusion in the final amendment. See also the discussion of public involvement opportunities in Section III.B.

One commenter suggested that the proposed categorical exclusion would be more appropriately placed as a clarifying statement elsewhere in the regulations, to note that transportation may be an implicit part of any action that is eligible for a categorical exclusion or to require, as an integral element of any categorical exclusion, that transportation be conducted in accordance with applicable regulatory requirements. Other commenters stated that transportation is a connected activity and should not be considered independently.

DOE's NEPA regulations currently state that a categorically excluded class of actions includes activities foreseeably necessary to proposals encompassed within the class of actions and provides ''associated transportation activities'' as one of two examples (§ 1021.410(d)). Categorical exclusion B1.30, however, applies to transfer actions where the predominant activity is transportation.

DOE's existing NEPA regulations (appendix B(1)) also contain an integral element for categorical exclusions requiring that, in order to be categorically excluded, an action not threaten a violation of applicable statutory, regulatory, or permit requirements for environment, safety, and health, including requirements of DOE orders.

One commenter asked DOE to clarify whether this categorical exclusion could be applied to the transfer of waste from a DOE site to an offsite, non-DOE facility that treats that type of waste. DOE believes that B1.30 does cover these types of transfer actions, as long as all the conditions of the categorical exclusion, including the integral elements, are satisfied and there are no extraordinary circumstances.

• Proposed B1.32 Restoration, creation, or enhancement of small wetlands.

One commenter supported DOE's strategy, stated in the preamble to the proposed rule, to coordinate activities in wetlands with state and federal agencies to assure compliance with other land use plans. The commenter suggested that wetland creation should address the impacts of attracting migratory wildlife, especially types of wildlife that are likely to be hunted for human consumption. Other commenters questioned how the terms ''small'' and ''large'' were defined and how size would be used to determine whether wetland restoration, creation, or enhancement would have significant impacts. Other commenters stated that this categorical exclusion should include compliance with all appropriate Federal environmental laws and regulations and that DOE should consider limiting the number of such projects to reduce the potential for cumulative adverse impacts.

DOE has reconsidered its proposal to categorically exclude restoration, creation, or enhancement of a small wetland. Actions typically taken by DOE to restore, enhance, or create a wetland normally would be performed as mitigation to compensate for loss or degradation of other wetlands as a result of a DOE proposed action. As such, wetland mitigation is not a separate or distinct action and should be considered as an integral part of the proposed action. Further, in those rare situations where DOE would undertake specific actions to restore, enhance, or create wetlands (e.g., development of

wetlands as part of wetland banking), the existing class of actions C9, which normally requires preparation of an environmental assessment, provides opportunity for other agency and public review and input into decisions regarding how the action should be undertaken. Accordingly, DOE is withdrawing its proposal to categorically exclude restoration, creation, or enhancement of a small wetland, as well as its proposal to make a conforming language change in C9.

• Proposed B1.33 (Final B1.32). Traffic flow adjustments, existing roads.

One commenter questioned whether DOE would extend the categorical exclusion to include road adjustments. This categorical exclusion is limited to DOE sites and applies only to adjustments of traffic flow, such as installation of traffic signs, signal lights, and turning lanes. It does not apply to general road adjustments, such as road widening and realignment. In order to clarify this point, DOE has modified this categorical exclusion to include turning lanes as an example of a categorically excluded action, and to specifically exclude general road adjustments.

The commenter also stated that increased traffic flow could result in increased risk of exposure to the public. DOE believes traffic flow adjustments could not, by their nature, alter traffic patterns in such a manner as to produce significantly increased public exposures. In response to a comment that commercial trucking terminals should be excluded, DOE notes that it does not operate commercial trucking terminals.

One commenter suggested adding this activity to B1.3 on routine maintenance. DOE does not consider traffic flow adjustments to constitute routine maintenance.

• Proposed B2.6 Packaging/transportation/storage of radioactive sources upon request by the Nuclear Regulatory Commission or other cognizant agency.

In response to several comments, DOE has clarified that ''other cognizant agency'' would include a state that regulates radioactive materials under an agreement with the Nuclear Regulatory Commission (Commission). In addition, DOE intends to include other agencies that may, under perhaps unusual circumstances, have responsibilities regarding the materials that are included in the categorical exclusion.

One commenter expressed concern that this categorical exclusion could apply to a wide variety of actions that private parties might conduct. DOE's NEPA implementing procedures, however, apply only to actions that DOE would conduct.

Another commenter expressed concern about cumulative effects from applying this categorical exclusion repeatedly. Because DOE is requested to perform the actions covered under B2.6 only occasionally—e.g., when a Commission licensee cannot or will not safely manage the material—DOE does not expect these activities to have significant cumulative effects. This commenter also stated that the justification for one of the examples cited in the proposed categorical exclusion—''packaged radioactive waste not exceeding 50 curies''—was not apparent and undefined as to impact. DOE possesses all the skills and equipment required to handle, transport, and store such materials safely, and would be involved in such activities only occasionally. Moreover, the Commission has found that its licensees normally possess and manage such materials without significant impacts. For these reasons, DOE believes it is appropriate to categorically exclude its activities regarding all of the materials the Commission has listed in 10 CFR 51.22(14).

Finally, a commenter suggested that DOE should apply the categorical exclusion to packaging, transportation, and storage of DOE's own radioactive materials that are the same kind as listed in the Commission's categorical exclusion. DOE is taking this suggestion under advisement and may consider it in a future rulemaking.

• Proposed Modification B3.6 Siting/construction/operation/decommissioning of facilities for bench-scale research, conventional laboratory operations, small-scale research and development and pilot projects.

DOE proposed to modify B3.6 (indoor bench-scale research projects) by combining it with B3.10 (small-scale research and development projects and small-scale pilot projects) and to include the siting, construction, operation, and decommissioning of facilities to house such projects. DOE also proposed to delete the descriptive phrase ''for generally less than two years'' in reference to the length of time a categorically excluded pilot project typically could be conducted.

One commenter stated that this categorical exclusion as proposed may be susceptible to abuse, e.g., by permitting a pilot project to evolve into a full-scale operation without public environmental review. DOE believes that this example would be a misapplication of the categorical exclusion. To clarify the meaning of ''pilot project,'' DOE is inserting the descriptive phrase ''generally less than two years.'' Thus, as revised, the only modification DOE is making to the existing categorical exclusions is combining B3.6 and B3.10, and expanding the combined categorical exclusion to include the siting, construction, operation, and decommissioning of facilities that would house the indoor bench-scale research, conventional laboratory operations, small-scale research and development, and small-scale pilot projects. DOE received no comments on these aspects of the proposed modification.

Several commenters questioned the definition of ''small-scale'' and ''pilot projects.'' One commenter questioned whether ''bench-scale'' includes the use of large pieces of equipment. The meaning of these terms is not changing from the existing regulations. DOE notes, however, that scale refers to the magnitude of the activity, e.g., the amount of materials consumed, waste produced, air emissions, and effluents. Further, the size of the equipment would be relevant in this context only if it affected the input of material and output of waste, so as to produce potentially significant physical impacts. See also the discussion of ''small-scale'' in Section III.E.

Another commenter expressed concern that the nature of research activities could involve new and untried processes. If a proposed research action had the potential to involve unique or unknown risks, then it would trigger the ''extraordinary circumstances'' provision in § 1021.410(b)(2), and thus would not be eligible for a categorical exclusion.

One commenter stated that there is an apparent conflict between B3.6 and C12. DOE notes that B3.6 specifically covers ''small-scale pilot projects (generally less than two years),'' constructed in an already developed area. C12, however, refers to larger scale, longer term projects that are not restricted to an already developed area. DOE is adding a specific reference to C12 in B3.6 to call attention to the differences between them.

• Proposed B3.10 Siting/construction/operation/decommissioning of particle accelerators, including electron beam accelerators, primary beam energy generally less than 100 MeV.

Two commenters recommended that DOE remove the word ''generally'' from the phrase ''generally less than 100 MeV,'' stating that the proposed language would permit categorically excluding much higher energy machines than 100 MeV (million electron-volts).

DOE has restated the condition to read ''less than approximately 100 MeV,'' which better reflects DOE's intention and addresses the commenters' concerns. See also the discussion in Section III.E.

Another commenter welcomed the proposed amendment and recommended adding to this proposed categorical exclusion ''maintenance and remedial actions [involving particle and electron beam accelerators] which have the incidental effect of improving machine performance within design criteria.'' DOE intends that the language of B3.10, as proposed, covers such actions as long as there is no increase in primary beam energy or current.

Finally, a commenter requested that the proposed categorical exclusion be restated in terms that relate to impacts such as land requirements and radioactive emissions rather than beam energy (i.e., 100 MeV) as proposed, stating that the proposed formulation would not be very meaningful to the public. Accelerators fitting this class of actions typically are room-size and often are installed in existing buildings at hospitals and universities. On the basis of its experience, the language of this proposed amendment, and the general restrictions on the application for categorical exclusions, particularly at § 1021.410 and the integral elements at appendix B, B(1)–B(4), DOE believes that the covered actions will not present any significant land use or radiation effects issues.

- Proposed B3.12 Siting/construction/operation/decommissioning of microbiological and biomedical facilities.

Several commenters expressed concern about the potential environmental, health, and socioeconomic impacts of microbiological and biomedical facilities and the lack of opportunity for public involvement. One commenter sought clarification regarding DOE's statement in the preamble to the proposed rulemaking that these facilities generally do not handle ''extremely dangerous materials.'' Another commenter urged DOE not to categorically exclude laboratories that are rated Biosafety Level 1 through 4.

All microbiological laboratories are rated Biosafety Level 1 through 4. Level 1 handles the least dangerous agents. To clarify what is intended by Biosafety Levels 1 and 2, the following definitions were extracted from Biosafety in Microbiological and Biomedical Laboratories, 3rd Edition, May 1993, U.S. Department of Health and Human Services Public Health Service, Centers for Disease Control and Prevention, and the National Institutes of Health: Publication No. (CDC) 93–8395. Biosafety Level 1 is assigned to facilities in which work is done with defined and characterized strains of viable microorganisms not known to cause disease in healthy adult humans (e.g., *Bacillus subtilis, Naeleria gruberi,* and infectious canine hepatitis). This designation represents a basic level of containment that relies on standard microbiological practices with no special primary or secondary barriers recommended, other than a sink for handwashing. Biosafety Level 2 is assigned to facilities in which work is done with the broad spectrum of indigenous moderate-risk agents present in the community and associated with human disease of varying severity (e.g., Hepatitis B virus, salmonellae and *Toxoplasma* spp.). This designation requires the use of splash shields, face protection, gowns and gloves, as appropriate, and the availability of secondary barriers such as handwashing facilities and laboratory waste decontamination facilities. Given these controls, DOE believes that it is appropriate to categorically exclude Biosafety Level 1 and 2 laboratories from further NEPA review, provided that all of the integral elements of a categorical exclusion (appendix B, B(1)–B(4)) are met.

Another commenter asked for a clarification of ''an already developed area.'' In particular, this commenter asked if it referred to a metropolitan area, residential area, commercially developed area, or existing biomedical facility. As discussed previously, ''an already developed area'' refers to an area ''where active utilities and currently used roads are readily accessible.'' DOE has clarified the categorical exclusion accordingly. Facilities that would be eligible for this categorical exclusion could be sited in a metropolitan, residential, or commercially developed area or in an existing biomedical facility, as long as the area is already developed.

- Proposed B3.13 Magnetic fusion experiments, no tritium fuel use.

A commenter asked whether DOE intends to conduct new magnetic fusion experiments at existing facilities under this proposed categorical exclusion, and indicated that an environmental assessment or environmental impact statement is required to protect the public and worker health and safety in light of impacts from exposure to electromagnetic fields. DOE intends to categorically exclude such experiments at existing facilities. Based on its experience with such activities, DOE believes that magnetic fusion experiments do not pose an electromagnetic field or other hazard to the public. DOE routinely provides workers with adequate training and controlled conditions to conduct such work safely.

- Proposed Modification B5.3 Modification (not expansion)/abandonment of oil storage access/brine injection/gas/geothermal wells, not part of site closure.

DOE proposed to add gas wells to this categorical exclusion, and one commenter stated that DOE should consider possible risks to public health and safety before doing so. This categorical exclusion applies only to the modification (e.g., installation of different chokes and other wellhead equipment) or abandonment of existing wells and does not include workover (see proposed B5.12) or expansion. Therefore, the inclusion of gas will not result in any significant impacts.

- Proposed Modification B5.5 Construction/operation of short crude oil/gas/steam/geothermal pipeline segments.

DOE proposed to add natural gas and steam pipelines and to remove references to the specific existing facilities to which the pipelines would be connected. One commenter expressed concern about the end point facilities of the pipeline segments and how such facilities would affect the impacts. The commenter stated that connecting pipeline segments without regard to the impacts of the end point facilities is comparable to approval of a sewer pipe without knowledge of the discharge point. DOE notes that this categorical exclusion applies to the construction and operation of short segments of pipelines between existing DOE facilities and existing transportation, storage, or refining facilities within a single industrial complex and within existing rights-of-way. Because both end points must be existing facilities, DOE believes that the potential impacts of constructing and operating short pipeline segments between such facilities do not depend on the type of facility and will not cause significant environmental impacts. There would be no discharges to the environment from these pipelines.

- Proposed Clarification B5.9. Temporary exemption for any electric powerplant;

- Proposed Clarification B5.10 Certain permanent exemptions for any existing electric powerplant;

- Proposed Clarification B5.11 Permanent exemption for mixed natural gas and petroleum;

• Proposed Modification (Removal) B5.12 Permanent exemption for new peakload powerplant;

• Proposed Modification (Removal) B5.13 Permanent exemption for emergency operations;

• Proposed Modification (Removal) B5.14 Permanent exemption for meeting scheduled equipment outages;

• Proposed Modification (Removal) B5.15 Permanent exemption due to lack of alternative fuel supply; and

• Proposed Modification (Removal) B5.16 Permanent exemption for new cogeneration powerplant.

DOE proposed to clarify or modify (i.e., remove) these categorical exclusions because they involve the grant or denial by DOE of certain exemptions under the Power Plant and Industrial Fuel Use Act of 1978 (PIFUA), which was amended by Congress and now applies only to base load power plants. It no longer applies to other types of power plants or to major fuel-burning installations. Some commenters opposed the retention of B5.9, B5.10, and B5.11 in their modified state on the basis that they appear to exempt multiple actions from an environmental assessment or environmental impact statement under the guise of energy conservation or expressed concerns about cumulative impacts, connected actions, or extraordinary circumstances. DOE believes that the original rationale for these categorical exclusions, based on experience with actual cases, remains valid and thus believes that they should be retained for situations where the law provides for exemptions (i.e., base load power plants). Another commenter expressed concern regarding the proposed removal of existing B5.12 through B5.16. While DOE acknowledges this concern, it is nonetheless appropriate for DOE to conform its NEPA regulations to changes in the law. These categorical exclusions are being clarified or removed from appendix B because under PIFUA, as amended, DOE no longer has authority to grant or deny PIFUA exemptions except in cases involving base load power plants.

• Proposed B5.12 Workover of existing oil/gas/geothermal well.

DOE proposed a new categorical exclusion covering the workover of existing oil, gas, or geothermal wells on existing wellpads where the work ''would not disturb adjacent habitat.'' One commenter requested that the word ''endanger'' be included in the proposed categorical exclusion. DOE believes that the words ''disturb'' and ''endanger'' are both subject to various interpretations. DOE is therefore modifying the categorical exclusion to use instead ''adversely affect,'' which reflects DOE's original intent and is consistent with language elsewhere in the DOE NEPA rule.

• Proposed Modification B6.1 Small-scale, short-term cleanup actions under RCRA, Atomic Energy Act, or other authorities.

DOE proposed to change the way in which it defines the scope of the categorical exclusion from ''removal actions under CERCLA * * * and removal-type actions similar in scope'' to ''small-scale, short-term cleanup actions under RCRA, the Atomic Energy Act, or other authorities'' without naming CERCLA. This proposal reflects DOE's policy (see Section III.B) of relying on the CERCLA process for review of actions to be taken under CERCLA. DOE believes that the reference in the current regulations to CERCLA removal actions is confusing in the context of this policy. DOE also proposed to expand the limits of the categorical exclusion to actions generally costing up to $5 million over as many as 5 years.

One commenter supported the modification to clarify application to RCRA cleanup actions and to increase the cost and time limitations. Another commenter stated that DOE should integrate the CERCLA and NEPA processes. As discussed in Section III.B, DOE's CERCLA/NEPA policy allows for case-by-case integration of the CERCLA and NEPA processes. Therefore, although CERCLA is not referenced in the new categorical exclusion, DOE may apply categorical exclusion B6.1 to certain CERCLA actions. DOE has not changed its proposed modification to the categorical exclusion based on this comment.

This commenter also requested that DOE retain the time and cost limits in the existing categorical exclusion (i.e., the CERCLA regulatory cost and time limits of $2 million and 12 months), but requested that if DOE does expand the limits to $5 million and 5 years as proposed, the language of the categorical exclusion should read ''expand the limits to'' and that the categorical exclusion's limits be stated as maximum cut off points. As discussed in Section III.E, DOE's use of numerical quantities are intended to provide a reasonable degree of flexibility and should not be applied as absolute limits. DOE has retained the proposed cost and time factors in the final categorical exclusion.

Another commenter stated that the applicability of a categorical exclusion to an action should be based on the site-specific conditions of the action, not on its cost or duration. The cost and time descriptions in the proposed categorical exclusion are simply indicators of the size and type of actions DOE intends to categorically exclude, not definitions of the actions themselves. Categorical exclusions listed in appendix B include integral elements that are site specific, and categorical exclusions will be applied based on site-specific factors, such as the existence of any extraordinary circumstances, rather than on the cost or duration of the action.

One commenter expressed concern that the use of terms ''small-scale,'' ''short-term,'' and ''generally'' are too subjective. The use of such descriptive terms is discussed in Section III.E.

One commenter requested that DOE state in example B6.1(b) that it would use the definition of hazardous waste from whichever regulatory agency (e.g., EPA or a state agency) provided the more protective definition for purposes of protecting public health and safety, or had greater authority to regulate hazardous waste. DOE proposed to revise the example to reflect the fact that hazardous waste is defined under one of two possible regulatory authorities, either 40 CFR Part 261 or applicable state requirements, depending on whether EPA or a state exercises primary regulatory authority. DOE does not have a choice as to which definition it must abide by. DOE is retaining the proposed language in the final categorical exclusion.

This commenter also stated that DOE did not specifically exempt high-level radioactive waste, transuranic waste, spent nuclear fuel, waste from reprocessing spent nuclear fuel, and uranium mill tailings in its language pertaining to waste cleanup and storage and requested clarification on the scope of the categorical exclusions in this regard. DOE agrees that it should clarify the scope of the categorical exclusion and has added the phrase ''other than high-level radioactive waste and spent nuclear fuel'' to the categorical exclusion. DOE believes that it can appropriately apply the categorical exclusion to cleanup activities involving transuranic waste and uranium mill tailings.

This commenter also expressed concern that this categorical exclusion allowed more discretionary authority to DOE for its waste management actions with less public notification, involvement, and accountability. DOE's response to comments relating to the reduction of public involvement opportunities is in Section III.B.

See also the discussion of categorical exclusion B6.9 for a modification of example B6.1(g).

• Proposed Modification (Removal) B6.4 Siting/construction/operation/decommissioning of facility for storing packaged hazardous waste for 90 days or less.

DOE proposed to replace the existing B6.4, which covers a very narrow class of waste storage actions, with a new and broader B6.4 that would have encompassed the activities to which the existing B6.4 applies. In response to comments on the proposed new B6.4, however, DOE has decided to narrow its scope in such a manner that retaining the existing B6.4 is necessary. Therefore, DOE is retaining the existing B6.4, and will list a new class of actions covering waste storage facilities (i.e., a ''reduced-scope'' version of the proposed B6.4) as B6.10. See the further discussion below.

• Proposed B6.4 (FinalB6.10) Siting/construction/operation/decommissioning of small waste storage facilities (not high-level radioactive waste, spent nuclear fuel).

Several commenters expressed concern that this proposed categorical exclusion could apply to actions that individually may have significant impacts and especially would have significant cumulative impacts if a number of such facilities were built. Commenters also expressed concern regarding the location of the facility, type of waste, and the nature of the surrounding environment. On the other hand, a commenter who supported the proposal suggested that DOE clarify that an unlimited number of 50,000 square-foot facilities could be built under the categorical exclusion.

DOE generally agrees with the commenters who stated that the proposal was too broad. However, DOE notes that significant new waste-producing activities and significant transfers of waste among sites are subject to NEPA analysis and would not be categorically excluded. Provisions for storing such waste would be within the scope of such analyses (or reviewed under CERCLA, if the waste would result from CERCLA environmental restoration activities), and storage impacts and alternatives would be appropriately assessed.

In light of the comments, DOE has decided to limit the applicability of proposed categorical exclusion B6.4 (final B6.10) to upgrades or replacement of storage facilities for waste that is already present at a DOE site at the time the storage capacity is to be provided. Providing new or upgraded storage facilities for existing wastes under this categorical exclusion would only improve upon previous storage conditions. Further, because the storage changes would not be associated with changes in waste type or waste quantity, providing new storage facilities or upgrades would not likely have cumulatively significant impacts. Storage facilities for newly generated waste from ongoing operations would not be categorically excluded, and any associated cumulative impacts would be considered in an appropriate NEPA analysis.

Several commenters questioned the basis for DOE's proposal to categorically exclude a particular size of storage facility, namely approximately 50,000 square feet or less. In recent years DOE has evaluated and constructed a variety of new waste storage facilities. These are typically uncomplicated light-weight buildings on a concrete pad floor that provide open floor storage space for waste packages. They are designed, and waste is emplaced, with safety as a priority. DOE chose 50,000 square feet as a representative size of such facilities, intending not to categorically exclude facilities that might be unusually large.

In response to commenters' objections regarding the word ''generally'' in the proposed phrase ''generally not to exceed an area of 50,000 square feet,'' DOE has changed the phrase to read ''less than approximately 50,000 square feet in area,'' which more accurately conveys DOE's original intent. See also the discussion in Section III.E.

As proposed, the categorical exclusion would not apply to storage of high-level radioactive waste or spent nuclear fuel. Several commenters questioned whether the categorical exclusion would apply to other types of waste. One commenter suggested that DOE not apply this categorical exclusion to transuranic wastes, fissile materials, and all other materials for which DOE is largely self-regulating. The commenter did not explain why self-regulation would be important to the determination at issue, and DOE believes that it is not. DOE has concluded, however, that storage facilities for wastes that require special precautions to prevent nuclear criticality should not be categorically excluded, and DOE is modifying the proposed categorical exclusion accordingly. For example, certain transuranic wastes that contain fissile materials may pose such concerns.

Finally, DOE has clarified its original intent to include under this categorical exclusion only storage facilities located at DOE sites, and also has deleted reference to ''activities connected to site operations,'' as commenters requested.

• Proposed Clarification B6.5 Siting/construction/operation/decommissioning of facility for characterizing/sorting packaged waste, overpacking waste (not high-level radioactive waste, spent nuclear fuel).

DOE proposed to clarify the existing B6.5 merely by adding cross-references to B6.4 and B6.6, not to change it substantively. A commenter, however, suggested that B6.5 should be expanded to include activities in which waste would be unpacked for purposes of characterization. DOE considers the comment to be outside the scope of this rulemaking, but may consider the suggestion in an appropriate future rulemaking.

• Proposed B6.9 Small-scale temporary measures to reduce migration of contaminated groundwater.

Several commenters expressed concern that, in effect, this categorical exclusion would reduce opportunities for review by other agencies and the public, and that it might be applied to actions that could have adverse effects on public health and the environment. One commenter stated that contamination of groundwater is a potentially significant risk to public health and that DOE should not exclude such contamination issues from public participation opportunities and NEPA documentation requirements. One commenter expressed concern that application of this categorical exclusion would eliminate valuable input from natural resource agencies regarding effects from actions of this type on state-designated priority habitats. A related comment expressed concern that actions categorically excluded under B6.9 could be detrimental to valuable habitat or cultural resources.

As noted in the preamble to the proposed rulemaking, DOE has found that these actions normally have very local and environmentally beneficial effects and pose no potential for significant environmental impacts. With regard to potential impacts to sensitive environmental resources (such as priority habitat and cultural resources), DOE believes that integral condition B(4) in appendix B, which states that an action proposed for categorical exclusion must not adversely affect environmentally sensitive areas, would preclude use of this categorical exclusion when priority habitat and cultural resources may be adversely affected. Public involvement opportunities are discussed in Section III.B.

One commenter stated that it was unclear why the proposed categorical exclusion was not within the scope of B6.1, an existing categorical exclusion for small-scale cleanup actions (see modification of B6.1 above). DOE believes that certain groundwater

cleanup actions could indeed be categorically excluded under B6.1, if the proposed actions met the conditions of that categorical exclusion, i.e., there were existing facilities to treat the water and the proposed activities were to be completed in about 5 years or less. DOE believes it is also appropriate, however, to categorically exclude the siting, construction, and longer term operation of groundwater treatment and containment facilities and therefore proposed a separate categorical exclusion (i.e., B6.9) to define and cover those activities. DOE intends that the categorical exclusion would include mobile pumping and treatment facilities or pumping and treatment facilities that might be built and then removed when the action was stopped, and DOE used the phrase ''small-scale temporary measure'' to characterize these possibilities. DOE has added these facility descriptions to the examples in the final categorical exclusion. DOE agrees that the example of ''installing underground barriers'' in the proposed categorical exclusion is more appropriately considered as an action under B6.1. For this reason, DOE is adding ''underground barriers'' to the existing example B6.1(g) and is deleting it from proposed B6.9.

Another commenter stated that the meaning of ''small-scale temporary measure'' was vague. DOE's use of terms such as ''small-scale'' is discussed in Section III.E.

Classes of Actions Listed in Appendix C

- Proposed Modification (Removal) C1 Major projects.

One commenter expressed concern that DOE's proposal to remove ''Major Projects, as designated by DOE Order 4240.1'' from appendix C would result in the categorical exclusion of proposed actions currently requiring an environmental assessment or environmental impact statement.

The term ''Major Project'' was defined in DOE Order 4240.1, based primarily on cost characteristics. DOE no longer uses the term ''Major Project,'' and thus the existing C1 is no longer meaningful. Accordingly, DOE is removing C1. DOE will continue to prepare environmental impact statements, however, for ''major Federal actions significantly affecting the quality of the human environment'' as required under NEPA § 102(2)(C). Also, although DOE has eliminated the designation of ''Major Projects'' from the proposed actions for which an environmental assessment would normally be prepared, DOE will continue to prepare environmental assessments for the types of proposed actions formerly included within the definition of ''Major Projects.''

- Proposed Modification C9 Restoration, creation, or enhancement of large wetlands.

DOE originally proposed to amend this category to conform to proposed B1.32, i.e., to distinguish NEPA review for large versus small wetlands. As noted in the discussion on B1.32, DOE is withdrawing its proposal to categorically exclude restoration, creation, or enhancement of a small wetland. Similarly, DOE is also withdrawing its proposal to make a conforming language change in C9.

- Proposed Modification (Removal) C10 Siting/construction/operation/ decommissioning of synchrotron radiation accelerator facility; and
- Proposed Modification C11 Siting/construction/operation/ decommissioning of low- or medium-energy particle acceleration facility with primary beam energy generally greater than 100 MeV.

DOE proposed to consolidate the existing C10 and C11 into C11 (reserving C10), and make the resulting C11 applicable for low to medium energy particle accelerators, consistent with the proposed categorical exclusion B3.10 for accelerators with energy less than approximately 100 MeV. One commenter stated that the existing regulations would have required an environmental impact statement under existing C1, which covers ''Major Projects,'' and DOE proposed to eliminate C1. The commenter is mistaken because ''Major Projects'' would normally have required an environmental assessment under C1, not an environmental impact statement. As noted above, DOE is removing C1. See previous discussion under C1.

- Proposed Modification C14 Siting/construction/operation of water treatment facilities generally greater than 250,000 gallons per day capacity.

DOE proposed to modify C14 to conform to proposed B1.26. A commenter objected to use of the word ''generally'' in both listings. DOE has replaced the phrase ''generally exceeding'' with ''greater than approximately,'' which reduces the agency's discretion, as the commenter requested, conforms with changes to proposed B1.26 discussed above, and better expresses DOE's original intent. DOE also revised C14 to include small wastewater and surface water treatment facilities, whose liquid discharges are not subject to external regulation, to conform with changes to proposed B1.26 made in response to comments. See also the discussion in Section III.E.

- Proposed Modification C16 Siting/construction/operation/ decommissioning of large waste storage facilities (not high-level radioactive waste, spent nuclear fuel).

DOE's proposed amendments were intended to clarify the meaning of ''onsite'' in the existing C16, and to make C16 consistent with proposed B6.4 (now final B6.10), under which a subset of small-scale actions included in existing C16 would be categorically excluded. DOE does not agree with a commenter's statements to the effect that this proposal would eliminate public participation for the siting of centralized and regional treatment and storage facilities and protect its contractors and itself at the expense of the public. DOE provides for appropriate public involvement in its environmental assessment process. In accordance with another commenter's suggestion, DOE is providing clearer direction by replacing the phrase ''generally greater than'' with ''greater than approximately,'' which also better expresses DOE's original intent. See also the discussion in Section III.E.

Classes of Actions Listed in Appendix D

- Proposed Modification D10 Siting/construction/operation/ decommissioning of major treatment, storage, and disposal facilities for high-level waste and spent nuclear fuel.

DOE proposed to amend D10 so that there would be no presumption that an EIS would be prepared for siting, constructing, operating, and decommissioning of onsite replacement storage facilities or upgrading storage facilities for spent nuclear fuel. DOE proposals for these types of facilities have varied too widely to support a general conclusion that such proposed actions normally require the preparation of an environmental impact statement. Thus, under DOE's proposal, onsite replacement or upgrade of storage facilities for spent nuclear fuel would no longer require the preparation of an environmental impact statement; rather, DOE would decide on a case-by-case basis (i.e., based on the particular project, site, and circumstances) whether to prepare an environmental assessment or an environmental impact statement. Contrary to one commenter's presumption, DOE's decision not to assign a particular level of NEPA documentation to onsite replacement or upgrading of storage facilities for spent nuclear fuel would never result in such activities being categorically excluded.

While one commenter supported the proposed modification, several others opposed it. Some commenters stated

that the use of the term ''major'' in D10 already provided DOE with the flexibility to prepare an environmental assessment in certain circumstances. In response, DOE notes that the term ''major'' refers to the size and/or cost of a particular project, not to whether its impacts will be significant. Thus, it is possible to have a large, costly DOE project that, because of its location or technical characteristics, is not likely to have significant environmental effects. In that case (such as replacement or upgrade of a spent nuclear fuel storage facility), DOE believes it is more appropriate to prepare an environmental assessment. Two commenters expressed concern that replacement or upgrade of spent nuclear fuel storage facilities could result in expanded spent nuclear fuel storage capacity and that existing storage sites may become long-term storage sites in the absence of a permanent repository. DOE did not intend to permit expanded storage under this exclusion and has modified its proposal to add ''where such replacement or upgrade will not result in increased storage capacity.'' Whether the storage of spent nuclear fuel may in fact become long-term storage is outside the scope of this rulemaking.

Another commenter stated that D10 must not be replaced by any less stringent process for public input and involvement. DOE will prepare either an environmental assessment or an environmental impact statement for replacement or upgrades of spent nuclear fuel storage facilities, depending on the circumstances. DOE provides for public involvement in both its environmental assessment and environmental impact statement processes.

Other commenters contended that DOE had proposed that an environmental assessment would be applicable for handling high-level waste. DOE's proposed modification deals with replacement and upgrades of storage facilities for spent nuclear fuel, not high-level waste. Under the original D10 and as amended, DOE would normally prepare an environmental impact statement for the siting, construction, operation, and decommissioning of major treatment, storage, and disposal facilities for high-level waste.

One commenter questioned why replacement or upgrades of high-level waste storage facilities are not treated the same as similar facilities for spent nuclear fuel, and whether DOE's proposed modification was designed to justify the preparation of an environmental assessment for a particular spent nuclear fuel facility at the Idaho National Engineering Laboratory, rather than an environmental impact statement. DOE's approach to formulating typical classes of actions for listing in subpart D is described in Section III.E, above. DOE does not formulate such classes of actions, or proposed additions and modifications, with the intention of securing coverage for a specific future or past action under a particular class of actions.

IV. Procedural Review Requirements

A. Environmental Review Under the National Environmental Policy Act

These amendments to the DOE NEPA rule establish, modify, and clarify procedures for considering the environmental effects of DOE actions within the Department's decision making process. Implementation of this rule will not affect the substantive requirements imposed on DOE or on applicants for DOE licenses, permits, and financial assistance, and this rule will not result in environmental impacts. Therefore, DOE has determined that this rule is covered by the categorical exclusion found at paragraph A6 of appendix A to subpart D, 10 CFR part 1021, which applies to procedural rulemaking. Accordingly, neither an environmental impact statement nor an environmental assessment is required.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 USC 601 et seq.) requires that an agency prepare an initial regulatory flexibility analysis to be published at the time the proposed rule is published. This requirement does not apply if the agency ''certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities'' (5 USC 603). The rule modifies existing policies and procedural requirements for DOE compliance with NEPA. The rule makes no substantive changes to requirements imposed on applicants for DOE licenses, permits, financial assistance, and similar actions as related to NEPA compliance. Therefore, DOE certifies that the rule will not have a ''significant economic impact on a substantial number of small entities.''

C. Review Under the Paperwork Reduction Act

No new information collection or recordkeeping requirements are imposed by these amendments. Accordingly, no Office of Management and Budget clearance is required under the Paperwork Reduction Act of 1980 (44 USC 3501 et seq.).

D. Review Under Executive Order 12612

Executive Order 12612, ''Federalism,'' 52 FR 41685 (October 30, 1987) requires that regulations be reviewed for Federalism effects on the institutional interest of states and local governments, and, if the effects are sufficiently substantial, preparation of a Federalism assessment is required to assist senior policymakers. These amendments will affect Federal NEPA compliance procedures, which are not subject to state regulation. The amendments will not have any substantial direct effects on states and local governments within the meaning of the Executive Order. Therefore, no Federalism assessment is required.

E. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, Section 3(a) of Executive Order 12988, ''Civil Justice Reform'' 61 FR 4729 (February 7, 1996), imposes on Executive agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity, (2) write regulations to minimize litigation, and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. With regard to the review required by Section 3(a), Section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in Section 3(a) and Section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, the final rule meets the relevant standards of Executive Order 12988.

F. Review Under Executive Order 12866

The final amendments were reviewed in accordance with Executive Order

12866, ''Regulatory Planning and Review,'' 58 FR 51735 (October 4, 1993), which requires a Federal agency to prepare a regulatory assessment, including the potential costs and benefits, of any ''significant regulatory action.'' The order defines ''significant regulatory action'' as any regulatory action that may have an annual effect on the economy of $100 million or more and may adversely affect the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments in a material way; create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; materially alter the budgetary impact of entitlements, grants, user fees, or loan programs; or raise novel legal or policy issues arising out of legal mandates (section 3(f)).

These amendments will modify already existing policies and procedures for compliance with NEPA. The amendments contain no substantive changes in the requirements imposed on applicants for a DOE license, financial assistance, permit, or similar actions. Therefore, DOE has determined that the incremental effect of these amendments to the DOE NEPA regulations will not have the magnitude of effects on the economy, or any other adverse effects, to bring this proposal within the definition of a ''significant regulatory action.''

G. Review Under the Unfunded Mandates Reform Act

Under section 205 of the Unfunded Mandates Reform Act of 1995 (2 USC 1533), Federal agencies are required to prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in the expenditure by state, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. Because the DOE NEPA regulations affect only DOE and do not create obligations on the part of any other person or government agency, neither state, local or tribal governments nor the private sector will be affected by amendments to these regulations. Therefore, DOE has determined that further review under the Unfunded Mandates Reform Act is not required.

H. Congressional Notification

The final regulations published today are subject to the Congressional notification requirements of Small Business Regulatory Enforcement Fairness Act of 1996 (Act) (5 USC 801). The Office of Management and Budget has determined that the final regulations do not constitute a ''major rule'' under the Act (5 USC 804). DOE will report to Congress on the promulgation of the final regulations prior to the effective date set forth at the beginning of this notice.

List of Subjects in 10 CFR Part 1021

Environmental impact statement.

Issued in Washington, DC, June 28, 1996.

Tara O'Toole,

Assistant Secretary, Environment, Safety and Health.

For reasons set out in the preamble, 10 CFR part 1021 is amended as follows:

PART 1021—NATIONAL ENVIRONMENTAL POLICY ACT IMPLEMENTING PROCEDURES

1. The authority citation for part 1021 continues to read as follows:

Authority: 42 U.S.C. 7254; 42 U.S.C. 4321 et seq.

§ 1021.104 [Amended]

2. In § 1021.104(b), the definition for *EIS Implementation Plan* is removed.

3. Section 1021.105 is revised to read as follows:

§ 1021.105 Oversight of Agency NEPA activities.

The Assistant Secretary for Environment, Safety and Health, or his/her designee, is responsible for overall review of DOE NEPA compliance. Further information on DOE's NEPA process and the status of individual NEPA reviews may be obtained upon request from the Office of NEPA Policy and Assistance, U.S. Department of Energy, 1000 Independence Avenue, SW, Washington, DC 20585–0119.

4. Section 1021.310 is revised to read as follows:

§ 1021.310 Environmental impact statements.

DOE shall prepare and circulate EISs and related RODs in accordance with the requirements of the CEQ Regulations, as supplemented by this subpart. DOE shall include in draft and final EISs a disclosure statement executed by any contractor (or subcontractor) under contract with DOE to prepare the EIS document, in accordance with 40 CFR 1506.5(c).

§ 1021.311 [Amended]

5. Section 1021.311 is amended by removing paragraph (f) and redesignating paragraph (g) as paragraph (f).

* * * * *

§ 1021.312 [Removed and reserved]

6. Section 1021.312 is removed and reserved.

7. In § 1021.315 paragraphs (b) and (d) are revised and (e) is added to read as follows:

§ 1021.315 Records of decision.

* * * * *

(b) If DOE decides to take action on a proposal covered by an EIS, a ROD shall be prepared as provided at 40 CFR 1505.2 (except as provided at 40 CFR 1506.1 and § 1021.211 of this part).

* * * * *

(d) No action shall be taken until the decision has been made public. DOE may implement the decision before the ROD is published in the Federal Register if the ROD has been signed and the decision and the availability of the ROD have been made public by other means (e.g., press release, announcement in local media).

(e) DOE may revise a ROD at any time, so long as the revised decision is adequately supported by an existing EIS. A revised ROD is subject to the provisions of paragraphs (b), (c), and (d) of this section.

§ 1021.322 [Amended]

8. Section 1021.322 is amended by removing paragraph (b)(1), and redesignating paragraphs (b)(2) through (b)(5) as paragraphs (b)(1) through (b)(4).

9. Appendix A to Subpart D, paragraph A7, is revised to read as follows:

Appendix A to Subpart D to Part 1021—Categorical Exclusions Applicable to General Agency Actions

* * * * *

A7 Transfer, lease, disposition, or acquisition of interests in personal property (e.g., equipment and materials) or real property (e.g., permanent structures and land), if property use is to remain unchanged; i.e., the type and magnitude of impacts would remain essentially the same.

* * * * *

10. Appendix B to Subpart D, is amended to revise the Table of Contents entries for B1.8, B1.13, B1.22, B3.6, B3.10, B5.3, B5.5, B5.9, B5.10, B5.12, B6.1, and B6.5; add B1.23 through B1.32, B2.6, B3.12, B3.13, B6.9, and B6.10; and remove B5.13 through B5.16, to read as follows:

Appendix B to Subpart D to Part 1021–Categorical Exclusions Applicable to Specific Agency Actions

Table of Contents

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B1.8 Modifications to screened water intake/outflow structures

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B1.13 Construction/acquisition/relocation of onsite pathways, short onsite access roads/railroads

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B1.22 Relocation of buildings

B1.23 Demolition/disposal of buildings

B1.24 Transfer of structures/residential, commercial, industrial use

B1.25 Transfer of land/habitat preservation, wildlife management

B1.26 Siting/construction/operation/decommissioning of small water treatment facilities, less than approximately 250,000 gallons per day capacity

B1.27 Disconnection of utilities

B1.28 Minor activities to place a facility in an environmentally safe condition, no proposed uses

B1.29 Siting/construction/operation/decommissioning of small onsite disposal facility for construction and demolition waste

B1.30 Transfer actions

B1.31 Relocation/operation of machinery and equipment

B1.32 Traffic flow adjustments, existing roads

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B2.6 Packaging/transportation/storage of radioactive sources upon request by the Nuclear Regulatory Commission or other cognizant agency

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B3.6 Siting/construction/operation/decommissioning of facilities for bench-scale research, conventional laboratory operations, small-scale research and development and pilot projects

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B3.10 Siting/construction/operation/decommissioning of particle accelerators, including electron beam accelerators, primary beam energy less than approximately 100 MeV

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B3.12 Siting/construction/operation/decommissioning of microbiological and biomedical facilities

B3.13 Magnetic fusion experiments, no tritium fuel use

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B5.3 Modification (not expansion)/abandonment of oil storage access/brine injection/gas/geothermal wells, not part of site closure

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B5.5 Construction/operation of short crude oil/gas/steam/geothermal pipeline segments

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B5.9 Temporary exemption for any electric powerplant

B5.10 Certain permanent exemptions for any existing electric powerplant

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B5.12 Workover of existing oil/gas/geothermal well

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B6.1 Small-scale, short-term cleanup actions under RCRA, Atomic Energy Act, or other authorities

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B6.5 Siting/construction/operation/decommissioning of facility for characterizing/sorting packaged waste, overpacking waste

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B6.9 Small-scale temporary measures to reduce migration of contaminated groundwater

B6.10 Siting/construction/operation/decommissioning of small upgraded or replacement waste storage facilities

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11. Appendix B to Subpart D, section B is amended by revising paragraphs B(1), B(2), and B(4)(iii) to read as follows:

B. Conditions That are Integral Elements of the Classes of Actions in Appendix B

* * * * *

(1) Threaten a violation of applicable statutory, regulatory, or permit requirements for environment, safety, and health, including requirements of DOE and/or Executive Orders.

(2) Require siting and construction or major expansion of waste storage, disposal, recovery, or treatment facilities (including incinerators), but the proposal may include categorically excluded waste storage, disposal, recovery, or treatment actions.

* * * * *

(4) * * *

(iii) Wetlands regulated under the Clean Water Act (33 U.S.C. 1344) and floodplains;

* * * * *

12. Appendix B to Subpart D, section B1, is amended by revising the introductory text to paragraph B1.3, paragraphs B1.3(n) and (o), B1.8, B1.13, B1.15, B1.18, B1.21, and B1.22, and adding paragraphs B1.23 through B1.32, to read as follows:

B1. Categorical Exclusions Applicable to Facility Operation

* * * * *

B1.3 Routine maintenance activities and custodial services for buildings, structures, rights-of-way, infrastructures (e.g., pathways, roads, and railroads), vehicles and equipment, and localized vegetation and pest control, during which operations may be suspended and resumed. Custodial services are activities to preserve facility appearance, working conditions, and sanitation, such as cleaning, window washing, lawn mowing, trash collection, painting, and snow removal. Routine maintenance activities, corrective (that is, repair), preventive, and predictive, are required to maintain and preserve buildings, structures, infrastructures, and equipment in a condition suitable for a facility to be used for its designated purpose. Routine maintenance may result in replacement to the extent that replacement is in kind and is not a substantial upgrade or improvement. In kind replacement includes installation of new components to replace outmoded components if the replacement does not result in a significant change in the expected useful life, design capacity, or function of the facility. Routine maintenance does not include replacement of a major component that significantly extends the originally intended useful life of a facility (for example, it does not include the replacement of a reactor vessel near the end of its useful life). Routine maintenance activities include, but are not limited to:

* * * * *

(n) Routine testing and calibration of facility components, subsystems, or portable equipment (including but not limited to, control valves, in-core monitoring devices, transformers, capacitors, monitoring wells, lysimeters, weather stations, and flumes); and

(o) Routine decontamination of the surfaces of equipment, rooms, hot cells, or other interior surfaces of buildings (by such activities as wiping with rags, using strippable latex, and minor vacuuming), including removal of contaminated intact equipment and other materials (other than spent nuclear fuel or special nuclear material in nuclear reactors).

* * * * *

B1.8 Modifications to screened water intake and outflow structures such that intake velocities and volumes and water effluent quality and volumes are consistent with existing permit limits.

* * * * *

B1.13 Construction, acquisition, and relocation of onsite pathways and short onsite access roads and railroads.

* * * * *

B1.15 Siting, construction (or modification), and operation of support buildings and support structures (including, but not limited to, trailers and prefabricated buildings) within or contiguous to an already developed area (where active utilities and currently used roads are readily accessible). Covered support buildings and structures include those for office purposes; parking; cafeteria services; education and training; visitor reception; computer and data processing services; employee health services or recreation activities; routine maintenance activities; storage of supplies and equipment for administrative services and routine maintenance activities; security (including security posts); fire protection; and similar support purposes, but excluding facilities for waste storage activities, except as provided in other parts of this appendix.

* * * * *

B1.18 Siting, construction, and operation of additional water supply wells (or replacement wells) within an existing well field, or modification of an existing water supply well to restore production, if there would be no drawdown other than in the immediate vicinity of the pumping well, no

resulting long-term decline of the water table, and no degradation of the aquifer from the new or replacement well.

* * * * *

B1.21 Noise abatement measures, such as construction of noise barriers and installation of noise control materials.

B1.22 Relocation of buildings (including, but not limited to, trailers and prefabricated buildings) to an already developed area (where active utilities and currently used roads are readily accessible).

B1.23 Demolition and subsequent disposal of buildings, equipment, and support structures (including, but not limited to, smoke stacks and parking lot surfaces).

B1.24 Transfer, lease, disposition or acquisition of interests in uncontaminated permanent or temporary structures, equipment therein, and only land that is necessary for use of the transferred structures and equipment, for residential, commercial, or industrial uses (including, but not limited to, office space, warehouses, equipment storage facilities) where, under reasonably foreseeable uses, there would not be any lessening in quality, or increases in volumes, concentrations, or discharge rates, of wastes, air emissions, or water effluents, and environmental impacts would generally be similar to those before the transfer, lease, disposition, or acquisition of interests. Uncontaminated means that there would be no potential for release of substances at a level, or in a form, that would pose a threat to public health or the environment.

B1.25 Transfer, lease, disposition or acquisition of interests in uncontaminated land for habitat preservation or wildlife management, and only associated buildings that support these purposes. Uncontaminated means that there would be no potential for release of substances at a level, or in a form, that would pose a threat to public health or the environment.

B1.26 Siting, construction (or expansion, modification, or replacement), operation, and decommissioning of small (total capacity less than approximately 250,000 gallons per day) wastewater and surface water treatment facilities whose liquid discharges are externally regulated, and small potable water and sewage treatment facilities.

B1.27 Activities that are required for the disconnection of utility services such as water, steam, telecommunications, and electrical power after it has been determined that the continued operation of these systems is not needed for safety.

B1.28 Minor activities that are required to place a facility in an environmentally safe condition where there is no proposed use for the facility. These activities would include, but are not limited to, reducing surface contamination, and removing materials, equipment or waste, such as final defueling of a reactor, where there are adequate existing facilities for the treatment, storage, or disposal of the materials, equipment or waste. These activities would not include conditioning, treatment, or processing of spent nuclear fuel, high-level waste, or special nuclear materials.

B1.29 Siting, construction, operation, and decommissioning of a small (less than approximately 10 acres) onsite disposal facility for construction and demolition waste which would not release substances at a level, or in a form, that would pose a threat to public health or the environment. These wastes, as defined in the Environmental Protection Agency's regulations under the Resource Conservation and Recovery Act, specifically 40 CFR 243.101, include building materials, packaging, and rubble.

B1.30 Transfer actions, in which the predominant activity is transportation, and in which the amount and type of materials, equipment or waste to be moved is small and incidental to the amount of such materials, equipment, or waste that is already a part of ongoing operations at the receiving site. Such transfers are not regularly scheduled as part of ongoing routine operations.

B1.31 Relocation of machinery and equipment, such as analytical laboratory apparatus, electronic hardware, maintenance equipment, and health and safety equipment, including minor construction necessary for removal and installation, where uses of the relocated items will be similar to their former uses and consistent with the general missions of the receiving structure.

B1.32 Traffic flow adjustments to existing roads at DOE sites (including, but not limited to, stop sign or traffic light installation, adjusting direction of traffic flow, and adding turning lanes). Road adjustments such as widening or realignment are not included.

13. Appendix B to Subpart D, section B2, is amended by adding B2.6, to read as follows:

B2. Categorical Exclusions Applicable to Safety and Health

* * * * *

B2.6 Packaging, transportation, and storage of radioactive materials from the public domain, in accordance with the Atomic Energy Act upon a request by the Nuclear Regulatory Commission or other cognizant agency, which would include a State that regulates radioactive materials under an agreement with the Nuclear Regulatory Commission or other agencies that may, under unusual circumstances, have responsibilities regarding the materials that are included in the categorical exclusion. Covered materials are those for which possession and use by Nuclear Regulatory Commission licensees has been categorically excluded under 10 CFR 51.22(14) or its successors. Examples of these radioactive materials (which may contain source, byproduct or special nuclear materials) are density gauges, therapeutic medical devices, generators, reagent kits, irradiators, analytical instruments, well monitoring equipment, uranium shielding material, depleted uranium military munitions, and packaged radioactive waste not exceeding 50 curies.

14. Appendix B to Subpart D, section B3, is amended by revising the introductory text to paragraph B3.1, B3.3, B3.6, and B3.10, and adding new paragraphs B3.12 and B3.13, to read as follows:

B3. Categorical Exclusions Applicable to Site Characterization, Monitoring, and General Research

B3.1 Onsite and offsite site characterization and environmental monitoring, including siting, construction (or modification), operation, and dismantlement or closing (abandonment) of characterization and monitoring devices and siting, construction, and associated operation of a small-scale laboratory building or renovation of a room in an existing building for sample analysis. Activities covered include, but are not limited to, site characterization and environmental monitoring under CERCLA and RCRA. Specific activities include, but are not limited to:

* * * * *

B3.3 Field and laboratory research, inventory, and information collection activities that are directly related to the conservation of fish or wildlife resources and that involve only negligible habitat destruction or population reduction.

* * * * *

B3.6 Siting, construction (or modification), operation, and decommissioning of facilities for indoor bench-scale research projects and conventional laboratory operations (for example, preparation of chemical standards and sample analysis); small-scale research and development projects; and small-scale pilot projects (generally less than two years) conducted to verify a concept before demonstration actions. Construction (or modification) will be within or contiguous to an already developed area (where active utilities and currently used roads are readily accessible). See also C12.

* * * * *

B3.10 Siting, construction, operation, and decommissioning of a particle accelerator, including electron beam accelerator with primary beam energy less than approximately 100 MeV, and associated beamlines, storage rings, colliders, and detectors for research and medical purposes, within or contiguous to an already developed area (where active utilities and currently used roads are readily accessible), or internal modification of any accelerator facility regardless of energy that does not increase primary beam energy or current.

* * * * *

B3.12 Siting, construction (or modification), operation, and decommissioning of microbiological and biomedical diagnostic, treatment and research facilities (excluding Biosafety Level-3 and Biosafety Level-4; reference: Biosafety in Microbiological and Biomedical Laboratories, 3rd Edition, May 1993, U.S. Department of Health and Human Services Public Health Service, Centers of Disease Control and Prevention, and the National Institutes of Health (HHS Publication No. (CDC) 93–8395)) including, but not limited to, laboratories, treatment areas, offices, and storage areas, within or contiguous to an already developed area (where active utilities and currently used roads are readily accessible). Operation may include the purchase, installation, and operation of biomedical equipment, such as commercially

available cyclotrons that are used to generate radioisotopes and radiopharmaceuticals, and commercially available biomedical imaging and spectroscopy instrumentation.

B3.13 Performing magnetic fusion experiments that do not use tritium as fuel, with existing facilities (including necessary modifications).

15. Appendix B to Subpart D, section B5, is amended by revising paragraphs B5.3, B5.5 and B5.9 through B5.12 and removing B5.13 through B5.16, to read as follows:

B5. Categorical Exclusions Applicable to Conservation, Fossil, and Renewable Energy Activities

* * * * *

B5.3 Modification (but not expansion) or abandonment (including plugging), which is not part of site closure, of crude oil storage access wells, brine injection wells, geothermal wells, and gas wells.

* * * * *

B5.5 Construction and subsequent operation of short crude oil, steam, geothermal, or natural gas pipeline segments between DOE facilities and existing transportation, storage, or refining facilities within a single industrial complex, if the pipeline segments are within existing rights-of-way.

* * * * *

B5.9 The grant or denial of any temporary exemption under the Powerplant and Industrial Fuel Use Act of 1978 for any electric powerplant.

B5.10 The grant or denial of any permanent exemption under the Powerplant and Industrial Fuel Use Act of 1978 of any existing electric powerplant other than an exemption under (1) section 312(c) relating to cogeneration, (2) section 312(l) relating to scheduled equipment outages, (3) section 312(b) relating to certain state or local requirements, and (4) section 312(g) relating to certain intermediate load powerplants.

B5.11 The grant or denial of a permanent exemption from the prohibitions of Title II of the Powerplant and Industrial Fuel Use Act of 1978 for any new electric powerplant to permit the use of certain fuel mixtures containing natural gas or petroleum.

B5.12 Workover (operations to restore production, such as deepening, plugging back, pulling and resetting lines, and squeeze cementing) of an existing oil, gas, or geothermal well to restore production when workover operations will be restricted to the existing wellpad and not involve any new site preparation or earth work that would adversely affect adjacent habitat.

16. Appendix B to Subpart D, section B6, is amended by revising the introductory text to paragraph B6.1, paragraph B6.1 (b), (g), and (j), B6.5, and adding paragraphs B6.9 and B6.10, to read as follows:

B6. Categorical Exclusions Applicable to Environmental Restoration and Waste Management Activities

B6.1 Small-scale, short-term cleanup actions, under RCRA, Atomic Energy Act, or other authorities, less than approximately 5 million dollars in cost and 5 years duration, to reduce risk to human health or the environment from the release or threat of release of a hazardous substance other than high-level radioactive waste and spent nuclear fuel, including treatment (e.g., incineration), recovery, storage, or disposal of wastes at existing facilities currently handling the type of waste involved in the action. These actions include, but are not limited to:

* * * * *

(b) Removal of bulk containers (for example, drums, barrels) that contain or may contain hazardous substances, pollutants, contaminants, CERCLA-excluded petroleum or natural gas products, or hazardous wastes (designated in 40 CFR part 261 or applicable state requirements), if such actions would reduce the likelihood of spillage, leakage, fire, explosion, or exposure to humans, animals, or the food chain;

* * * * *

(g) Confinement or perimeter protection using dikes, trenches, ditches, diversions, or installing underground barriers, if needed to reduce the spread of, or direct contact with, the contamination;

* * * * *

(j) Segregation of wastes that may react with one another or form a mixture that could result in adverse environmental impacts;

* * * * *

B6.5 Siting, construction (or modification or expansion), operation, and decommissioning of an onsite facility for characterizing and sorting previously packaged waste or for overpacking waste, other than high-level radioactive waste, if operations do not involve unpacking waste. These actions do not include waste storage (covered under B6.4, B6.6, B6.10, and C16) or the handling of spent nuclear fuel.

* * * * *

B6.9 Small-scale temporary measures to reduce migration of contaminated groundwater, including the siting, construction, operation, and decommissioning of necessary facilities. These measures include, but are not limited to, pumping, treating, storing, and reinjecting water, by mobile units or facilities that are built and then removed at the end of the action.

B6.10 Siting, construction (or modification), operation, and decommissioning of a small upgraded or replacement facility (less than approximately 50,000 square feet in area) at a DOE site within or contiguous to an already developed area (where active utilities and currently used roads are readily accessible) for storage of waste that is already at the site at the time the storage capacity is to be provided. These actions do not include the storage of high-level radioactive waste, spent nuclear fuel or any waste that requires special precautions to prevent nuclear criticality. See also B6.4, B6.5, B6.6, and C16.

17. Appendix C to Subpart D is amended in the Table of Contents by removing and reserving the entries for C1 and C10 and by revising the entries for C11, C14 and C16 to read as follows:

Appendix C to Subpart D to Part 1021—Classes of Actions That Normally Require EAs But Not Necessarily EISs

Table of Contents

18. Appendix C to Subpart D to Part 1021 is amended by removing and reserving paragraphs C1 and C10 and by revising C11, C14 and C16, to read as follows:

C1 [Removed and reserved].

* * * * *

C10 [Removed and reserved].

C11 Siting, construction (or modification), operation, and decommissioning of a low- or medium-energy (but greater than approximately 100 MeV primary beam energy) particle acceleration facility, including electron beam acceleration facilities, and associated beamlines, storage rings, colliders, and detectors for research and medical purposes, within or contiguous to an already developed area (where active utilities and currently used roads are readily accessible).

* * * * *

C14 Siting, construction (or expansion), operation, and decommissioning of wastewater, surface water, potable water, and sewage treatment facilities with a total capacity greater than approximately 250,000 gallons per day, and of lower capacity wastewater and surface water treatment facilities whose liquid discharges are not subject to external regulation.

* * * * *

C16 Siting, construction (or modification to increase capacity), operation, and decommissioning of packaging and unpacking facilities (that may include characterization operations) and large storage facilities (greater than approximately 50,000 square feet in area) for waste, except high-level radioactive waste, generated onsite or resulting from activities connected to site operations. These actions do not include storage, packaging, or unpacking of spent nuclear fuel. See also B6.4, B6.5, B6.6, and B6.10.

19. Appendix D to Subpart D is amended to revise the Table of Contents

entries for D1 and D10 to read as follows:

Appendix D to Subpart D to Part 1021—Classes of Actions That Normally Require EISs

Table of Contents

D1 Strategic Systems

* * * * *

D10 Siting/construction/operation/decommissioning of major treatment, storage, and disposal facilities for high-level waste and spent nuclear fuel

* * * * *

20. Appendix D to subpart D to part 1021 is amended by revising paragraphs D1 and D10, to read as follows:

D1 Strategic Systems, as defined in DOE Order 430.1, ''Life-Cycle Asset Management,'' and designated by the Secretary.

* * * * *

D10 Siting, construction, operation, and decommissioning of major treatment, storage, and disposal facilities for high-level waste and spent nuclear fuel, including geologic repositories, but not including onsite replacement or upgrades of storage facilities for spent nuclear fuel at DOE sites where such replacement or upgrade will not result in increased storage capacity.

* * * * *

[FR Doc. 96–17285 Filed 7–8–96; 8:45 am]

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July 9, 1996

Part V

Department of Housing and Urban Development

5 CFR Chapter LXV

24 CFR Part 0

Supplemental Standards of Ethical Conduct for Employees of the Department of Housing and Urban Development; Final Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

5 CFR Chapter LXV

24 CFR Part 0

[Docket No. FR–3331–F–01]

RIN 2501–AB55, 3209–AA15

Supplemental Standards of Ethical Conduct for Employees of the Department of Housing and Urban Development

AGENCY: Office of the Secretary, Department of Housing and Urban Development (HUD or Department).

ACTION: Final rule.

SUMMARY: The Department of Housing and Urban Development, with the concurrence of the Office of Government Ethics (OGE), is issuing a final rule establishing uniform standards of ethical conduct for employees of the Department to supplement the Standards of Ethical Conduct for Employees of the Executive Branch issued by OGE. The final rule is a necessary supplement to the executive branch-wide Standards because it addresses ethical issues unique to the Department. The final rule will become effective 30 days after the date of publication, and will establish regulations prohibiting certain financial interests and restricting certain outside employment.

EFFECTIVE DATE: This rule is effective on August 8, 1996.

FOR FURTHER INFORMATION CONTACT: Aaron Santa Anna, Assistant General Counsel, Ethics Law Division, 202–708–3815; or Sam E. Hutchinson, Associate General Counsel, Office of Human Resources Law, 202–708–0888. Hearing or speech-impaired individuals may call HUD's TDD number 202–708–3259. (Telephone numbers are not toll-free.)

SUPPLEMENTARY INFORMATION:

I. Background

On June 30, 1995, the Department, with OGE's concurrence, published for comment a proposed rule to establish supplemental standards of ethical conduct for HUD employees (60 FR 34420–34426). The proposed rule was intended to supplement the Standards of Ethical Conduct for Employees of the Executive Branch (Standards) published by OGE on August 7, 1992, and effective February 3, 1993 (57 FR 35006–35067, as corrected at 57 FR 48557, 57 FR 52583, and 60 FR 51667, with additional grace period extensions for certain exisiting agency standards of conduct at 59 FR 4779–4780, 60 FR 6390–6391, and 60 FR 66857–66858). The executive branch-wide Standards, codified at 5 CFR part 2635, establish uniform standards of ethical conduct for executive branch employees. The proposed rule was issued pursuant to 5 CFR 2635.105, which authorizes executive branch agencies to publish agency-specific supplemental regulations necessary to implement their respective ethics programs. The Department, with OGE's concurrence, determined that the supplemental regulations contained in the proposed rule were necessary to implement the Department's ethics program successfully, in light of the Department's unique programs and operations.

The proposed rule prescribed a 60-day comment period and invited comments from all interested parties. The Department received one public comment, and after careful consideration of it, has made appropriate modifications to the rule. In addition, the Department has made appropriate modifications to the rule based on various intra-departmental comments. The Department, with OGE's concurrence, is now publishing as a final rule the Supplemental Standards of Ethical Conduct for Employees of the Department of Housing and Urban Development, to be codified in a new chapter LXV of 5 CFR, consisting of part 7501.

II. Summary of the Comments

The Department received one public comment; it was from the Federal Home Loan Mortgage Corporation (''Freddie Mac''). The Department also received six intra-departmental comments. Freddie Mac's comments focused primarily on three distinct areas under the proposed rule: scope of coverage, ownership interests, and outside employment. The intra-departmental comments contained both requests for substantive changes and for additional clarification regarding the application of the rule in general or specific sections.

III. Analysis of the Comments

Section 7501.102 Definitions

One commenter within the Department recommended that one portion of the definition of ''security'' be modified to read that the term ''includes'' any right to acquire or dispose of any long or short term position in securites. The Department agrees that the suggested language is more reflective of the Department's intent than the originally proposed language and has, therefore, implemented this revision to the definition of ''security'' in § 7501.102 of the final rule.

Freddie Mac suggested that the Department include definitions for ''employee'' and ''special Government employee.'' The Department has not adopted this recommendation because the definitions of those terms in the executive branch-wide Standards, at 5 CFR 2635.102 (h) and (l), apply to supplemental regulations unless otherwise specified.

Section 7501.104 Prohibited Financial Interests

One commenter within the Department recommended that special Government employees assigned to work in one of the program offices listed in § 7501.106(b)(1) not be excluded from the coverage of the financial interest prohibitions in § 7501.104 of the rule, since such employees would have access to the same types of confidential information as would other employees in those officies. The Department has adopted this recommendation to protect against the appearance that any HUD employee is using confidential information for private gain. The proposed exclusion of special Government employees from the coverage of this section has been eliminated.

Another commenter within the Department recommended that the first sentence of the description of prohibited financial interests in real estate, at § 7501.104(a)(4), be amended to read: ''Stock or another financial interest in a multifamily project or single family dwelling, cooperative unit or condominium unit, which is owned or subsidized by the Department, or which is subject to a note and mortgage or other security instrument insured by the Secretary, except to the extent that the stock or other interest represents the employee's principal residence.'' The Department has decided to adopt this language as a better characterization of the Department's interest in various real estate interests covered by the final rule.

Section 7501.105 Outside Employment

One commenter within the Department recommended that the Department include a provision regarding an employee's service on the board of a non-Federal organization in an official capacity, similar to prior 24 CFR 0.735–210 of HUD's old departmental standards of conduct. In response, a Note has been added to this section to clarify that while service in an official capacity on the Board of a non-Federal organization is not outside employment or other activity subject to

this section, employees need to be aware that such service is subject to other applicable laws.

While generally supportive of the outside employment provisions in this section, Freddie Mac wanted the requirements in the section to extend to any type of writing by employees. The Department has included within the coverage of this section those types of outside employment which the Department believes pose the greatest potential for employees to engage in conduct which might violate applicable laws or regulations, and is not convinced that the suggested extension of coverage is warranted.

In addition, Freddie Mac suggested that the public impact of an outside activity in relation to the employee's official position be taken into consideration when deciding whether to grant a waiver, under § 7501.103 of the rule, from the prohibitions in this section. The specific inclusion of the suggested factors in the final rule is uncalled for, because the factors are largely covered by the terms of the waiver standard at § 7501.103, i.e., that application of the prohibition is not necessary to ensure public confidence in the impartiality and objectivity with which the Department's programs are administered.

Section 7501.106 Additional Rules for Certain Department Employees Involved in the Regulation or Oversight of Government Sponsored Enterprises

Freddie Mac noted that the supplemental regulation is not specifically applicable to individuals who serve pursuant to a consulting agreement with the Department. The Department has decided not to make the regulation specifically applicable to consultants, since the generic term ''consultants'' may include individuals who are independent contractors as well as those who are deemed employees of the Department. Whether a consultant will be deemed an employee of the Department for these purposes depends on various factors, including the type of functions or activities being performed by the consultant for the Department, and the extent of the consultant's supervision by an officer or employee of the Department. A consultant deemed an employee of the Department would be subject to the executive branch-wide Standards and these rules.

Freddie Mac also recommended that the description of prohibited financial interests in § 7501.106(c)(ii) be amended to parallel the description of prohibited financial interests in § 7501.104(a), by adding the terms ''issued'' and ''collateralized'' in the description of prohibited securities in a mortgage institution, a certain percentage of whose originated mortgages involve the Federal National Mortgage Association or Freddie Mac in various specified capacities. This recommendation was adopted to attain uniformity.

A commenter within the Department suggested that employees of the Office of Inspector General and all employees of the Office of Federal Housing Enterprise Oversight be included in the list at § 7501.106(b)(1) of employees covered by the prohibition in this section. The Department has adopted this recommendation to make the prohibitions contained in § 7501.106 uniformly applicable to all employees whose official duties require that they have access to information regarding a Government sponsored enterprise (GSE). Similarly, another commenter within the Department recommended that the Department's Office of Lead-Based Paint and Poisoning Prevention be excluded from coverage under § 7501.106(b)(1), since it is not involved in the regulation or oversight of GSEs. This recommendation was adopted for the reason asserted by the commenter.

This same commenter also recommended that the definition of mortgage institution be amended to include entities that insure mortgages. The Department has adopted this recommendation as a more specific reflection of its intent. In addition, the Department has adopted this commenter's recommendation that an institution's most recent annual financial statement be used to determine whether it exceeds the thresholds contained in § 7501.106(c)(1).

This same commenter also expressed concern that the definition of covered employee in § 7501.106(b)(1), which encompasses only employees who are required to file financial disclosure reports, excludes many employees whose primary job responsibilities significantly include the regulation or oversight of GSEs. To address this concern, the Department has modified proposed § 7501.106(b)(1)(viii) to include the DAEO in the list of those individuals who may designate an employee as a ''covered employee'' to ensure compliance with the principles set forth in 5 CFR 2635.403. To ensure that the prohibition in this section is not unnecessarily burdensome, the Department has also added a new § 7501.106(b)(2) (the prior proposed paragraph (b)(2) has been redesignated paragraph (b)(3)), which permits the DAEO, upon recommendation of the appropriate individual of Assistant Secretary rank, to exclude in writing an employee otherwise designated as a ''covered employee'' if the employee's official duties do not substantially involve the regulation or oversight of GSEs and ownership of the interests prohibited by § 7501.106(c) would not cause a reasonable person to question the impartiality and objectivity with which the Department's programs are administered.

In response to another comment from within the Department, the Department has specifically included the Federal National Mortgage Association and the Federal Home Loan Mortgage Corporation under § 7501.106(e) to make clear that special Government employees who are covered employees under § 7501.106(b)(1) cannot be employed by any of these organizations or their affiliates. This modification is required to ensure compliance with 5 CFR 2635.403 and because special Government employees are not otherwise subject to the outside employment and other activities provisions of § 7501.105.

IV. Other Changes

An exception is being added to the prohibition in § 7501.104(a)(5) against an employee receiving any Department subsidy provided pursuant to Section 8 of the United States Housing Act of 1937, as amended (42 U.S.C. 1437f). Under new § 7501.104(a)(5)(iii), an employee may receive such a subsidy if the tenant of the subsidized unit is the parent, child, grandchild, or sibling of the employee, but only if there is no increase in that tenant's rent upon the commencement of subsidy payments other than normal annual adjustments. This change from the proposed rule reflects current Departmental practice.

In addition, the Department has decided to exclude special Government employees (SGEs) from the prior approval requirement at § 7501.105(c) of the final rule. Proposed § 7501.105(c)(1) would have required all employees of the Department to obtain approval before engaging in certain types of outside employment or activities. Special Government Employees have been subject to this requirement because they are included within the meaning of ''employee,'' as used in the supplemental regulation. However, SGEs were not required to obtain prior approval for outside employment under the Department's old Standards of Conduct. Moreover, SGEs are excluded from the outside employment prohibitions at § 7501.105(a) of the final rule. Accordingly, the Department has concluded that it would be unreasonable to apply the prior approval requirement to SGEs, and is providing in § 7501.103(c)(1) of the final

rule that the prior approval requirement therein applies to employees of the Department, ''except special Government employees.''

Finally, the Department has decided not to exclude employees who file public or confidential financial disclosure reports in the Office of Housing's Office of Deputy Assistant Secretary for Operations from the list of ''covered employees'' in § 7501.106(b)(1). Section 7501.106 sets forth additional rules for certain employees involved in the regulation or oversight of the Government sponsored enterprises. The reason for this change is that the Office of Housing has been reorganized since the publication of the proposed rule to give the Deputy Assistant Secretary for Operations programmatic responsibility over matters that affect the Government sponsored enterprises. Accordingly, the exclusionary clause ''with the exception of the Office of Deputy Assistant Secretary for Operations'' has been deleted from paragraph (b)(1)(ii) containing the definition of ''covered employee'' for purposes of § 7501.106.

V. Removal of Old Department Standards of Conduct Regulations and Revision of the Residual Cross-Reference Provision

On April 5, 1996, the Department published a final rule that provided for removal of all of the then existing provisions in the Department's old Standards of Conduct regulation at 24 CFR part 0, and their replacement with a single section that provides a cross-reference to 5 CFR parts 2634 and 2635, effective May 6, 1996 (61 FR 15350). To prevent an untimely lapse in enforcement authority for the two sections of 24 CFR part 0 that had temporarily remained in effect pursuant to the extended grace periods in the Standards—§ 0.735–203 regarding outside employment and other activities, and § 0.735–204 regarding financial interests—the Department published a correction to the final rule on May 1, 1996, effective May 6, 1996, preserving those two sections at 24 CFR 0.2 and 0.3. (61 FR 19187–19188). Upon the effective date of the Department's supplemental standards of ethical conduct as a final rule, the Department is amending 24 CFR part 0 to remove the temporarily preserved sections regarding outside employment and financial interests, and to include in the residual cross-reference provision a notation of the Department's newly issued supplemental standards of ethical conduct at 5 CFR part 7501.

VI. Matters of Regulatory Procedure

Regulatory Flexibility Act

It is hereby certified that this rule will not have significant economic impact on a substantial number of small entities. This rule affects only Federal employees and their immediate families.

Environmental Impact

In accordance with 40 CFR 1508.4 of the regulations of the Council on Environmental Quality and 24 CFR 50.20(k) of the HUD regulations, the policies and procedures contained in this rule relate only to internal administrative procedures whose content does not constitute a development decision nor affect the physical condition of project areas or building sites, and therefore, are categorically excluded from the requirements of the National Environmental Policy 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 will not have substantial direct effects on States or their political subdivisions, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Specifically, this rule is only directed toward Federal employees and would not alter the established roles of HUD and the States and local governments. As a result, the rule is not subject to review under the order.

Executive Order 12606, The Family

The General Counsel, as the Designated Official under Executive Order 12606, *The Family*, has determined that this 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. No significant change in existing HUD policies or programs would result from promulgation of this rule, as those policies and programs relate to family concerns.

List of Subjects

5 CFR Part 7501

Conflict of interests, Government employees.

24 CFR Part 0

Administrative practice and procedure, Conflict of interests.

Dated: July 2, 1996.

Henry G. Cisneros,

Secretary of the Department of Housing and Urban Development.

Approved: July 2, 1996.

Stephen D. Potts,

Director, Office of Government Ethics.

For the reasons set forth in the preamble, the Department of Housing and Urban Development, with the concurrence of the Office of Government Ethics, is amending title 5 and title 24, subtitle A, of the Code of Federal Regulations as follows:

TITLE 5—[AMENDED]

1. A new chapter LXV, consisting of part 7501, is added to 5 CFR to read as follows:

CHAPTER LXV—DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

PART 7501—SUPPLEMENTAL STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Sec.

Authority: 5 U.S.C. 301, 7301, 7351, 7353; 5 U.S.C. App. (Ethics in Government Act of 1978); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306; 5 CFR 2635.105, 2635.203(a), 2635.403(a), 2635.803, 2635.807.

§ 7501.101 Purpose.

In accordance with 5 CFR 2635.105, the regulations in this part apply to employees of the Department of Housing and Urban Development (HUD or Department) and supplement the Standards of Ethical Conduct for Employees of the Executive Branch contained in 5 CFR part 2635. Employees are required to comply with 5 CFR part 2635, this part, and any additional rules of conduct that the Department is authorized to issue.

§ 7501.102 Definitions.

For purposes of this part, and otherwise as indicated, the following definitions shall apply:

Affiliate means any entity that controls, is controlled by, or is under common control with another entity.

Agency designee, as used also in 5 CFR part 2635, means the Associate General Counsel for Human Resources Law, the Assistant General Counsel,

Ethics Law Division, and the HUD Field Office Assistant General Counsels; the Inspector General, for employees assigned to the Office of the Inspector General; and the General Counsel, Office of Federal Housing Enterprise Oversight, for employees assigned to the Office of Federal Housing Enterprise Oversight.

Agency ethics official, as used also in 5 CFR part 2635, means the agency designees as specified above.

Assistance means any contract, grant, loan, subsidy, guarantee, cooperative agreement or other financial assistance under a program administered by the HUD Secretary, and includes ''assistance'' awarded by the Department that is competitively redistributed to a second tier of applicants or awardees. The term does not include single family mortgage insurance provided under a program administered by the Secretary.

Designated Agency Ethics Official (DAEO) means the General Counsel of HUD or the Deputy General Counsel (Operations) in the absence of the General Counsel.

Employment means any compensated or uncompensated form of non-Federal employment or business relationship, including self employment, involving the provision of personal services by the employee. It includes, but is not limited to, personal services as an officer, director, employee, agent, attorney, consultant, contractor, general partner, trustee, teacher or speaker. It includes writing when done under an arrangement with another person for production or publication of the written product.

Security means all interests in debt or equity instruments. The term includes, without limitation, secured and unsecured bonds, debentures, notes, securitized assets and commercial paper including loans securitized by mortgages or deeds of trust and securities backed by such instruments, as well as all types of preferred and common stock. The term encompasses current and contingent ownership interests including any beneficial or legal interest derived from a trust. Such interest includes any right to acquire or dispose of any long or short position in such securities and also includes, without limit, interests convertible into such securities, as well as options, rights, warrants, puts, calls and straddles with respect thereto. The term shall not, however, be construed to include deposit accounts.

§ 7501.103 Waivers.

The Designated Agency Ethics Official may waive any provision of this part upon finding that the waiver will not result in conduct inconsistent with 5 CFR part 2635 or otherwise prohibited by law and that application of the provision is not necessary to ensure public confidence in the impartiality and objectivity with which the Department's programs are administered. Each waiver shall be in writing and supported by a statement of the facts and findings upon which it is based and may impose appropriate conditions, such as requiring the employee's execution of a written disqualification statement.

§ 7501.104 Prohibited financial interests.

(a) *General requirement.* This section applies to all HUD employees except special Government employees who are not ''covered employees'' as defined in § 7501.106(b)(1) of this part. Except as provided in paragraph (b) of this section, an employee, or an employee's spouse or minor child, shall not directly or indirectly receive, acquire or own:

(1) Securities issued by the Federal National Mortgage Association (FNMA) or securities collateralized by FNMA securities;

(2) Securities issued by the Federal Home Loan Mortgage Corporation (FHLMC) or securities collateralized by FHLMC securities;

(3) Federal Housing Administration debentures or certificates of claim;

(4) Stock or another financial interest in a multifamily project or single family dwelling, cooperative unit, or condominium unit, which is owned or subsidized by the Department, or which is subject to a note or mortgage or other security interest insured by the Department, except to the extent that the stock or other interest represents the employee's principal residence. Employees who wish to purchase a Department-held property as a principal residence must adhere to the procedures established by the Assistant Secretary for Housing for the administration of the property disposition program set forth in HUD Handbook 4310.5;

(5) Any Department subsidy provided pursuant to Section 8 of the United States Housing Act of 1937, as amended, (42 U.S.C. 1437f) to or on behalf of a tenant of property owned by the employee. However, an employee may receive such a subsidy when:

(i) The employee acquires without specific intent, as through gift or inheritance, a property which at the time of acquisition has a tenant receiving such a subsidy, but only as long as that tenant continues to reside in the property;

(ii) An incumbent tenant who has not previously received such a subsidy becomes the beneficiary thereof, but only if there is no increase in that tenant's rent upon the commencement of subsidy payments other than normal annual adjustments; or

(iii) The tenant is the parent, child, grandchild, or sibling of the employee, but only if there is no increase in that tenant's rent upon the commencement of subsidy payments other than normal annual adjustments; or

(6) Any direct creditor interest in a mortgage insured by the Department.

(b) *Exception to prohibition for certain interests.* Nothing in this section prohibits an employee, or the spouse or minor child of an employee, from acquiring, owning, or controlling:

(1) An interest in a publicly traded or publicly available investment fund which, in its prospectus, does not indicate the objective or practice of concentrating its investments in resi dential mortgages or securities backed by residential mortgages, except those of the Government National Mortgage Association (GNMA), and the employee neither exercises control nor has the ability to exercise control over the financial interests held in the fund;

(2) A limited partnership interest in a partnership which has at least 5,000 partnership interests, and no more than 25% of the gross value of the partnership interest constitutes projects subject to HUD held or insured mortgages or projects currently receiving the benefit of HUD subsidies; or

(3) Mortgage insurance provided pursuant to section 203 of the National Housing Act (12 U.S.C. 1709) on the employee's principal residence and any one other single family residence.

(c) *Reporting and divestiture.* An employee must report, in writing, to the appropriate agency ethics official, any interest prohibited under paragraph (a) of this section acquired prior to the commencement of employment with the Department or without specific intent, as through gift, inheritance, or marriage, within 30 days from the start of employment or acquisition of such interest. Such interest must be divested within 90 days from the date reported unless waived by the Designated Agency Ethics Official in accordance with § 7501.103.

§ 7501.105 Outside employment.

(a) *Prohibited outside employment.* Subject to the exceptions set forth in paragraph (b) of this section, HUD employees, except special Government employees, shall not engage in:

(1) Employment involving active participation in a business dealing with or related to real estate or manufactured

housing including but not limited to real estate brokerage, management and sales, architecture, engineering, mortgage lending, property insurance, appraisal services, construction, construction financing, land planning, or real estate development;

(2) Employment with a person, other than a State or local government, who engages in lobbying activities concerning Department programs or who is required to report expenditures for lobbying activities or register as a lobbyist under 42 U.S.C. 3537b or similar statutes which require the registration of persons who attempt to influence the decisions of officers or employees of the Department;

(3) Employment as an officer or director of a person who is a Department-approved mortgagee, a lending institution or an organization which services securities for the Department; or

(4) Employment with the Federal National Mortgage Association, the Federal Home Loan Mortgage Corporation, the Federal Home Loan Bank System or any affiliate thereof.

(b) *Exceptions to employment prohibitions.* The prohibitions set forth in paragraph (a) of this section do not apply to serving as an officer or a member of the Board of Directors of:

(1) A Federal Credit Union;

(2) A cooperative or condominium association for a housing project which is not subject to regulation by the Department or, if so regulated, in which the employee personally resides; or

(3) An entity designated in writing by the Designated Agency Ethics Official.

(c) *Prior approval requirement.* (1) Employees, except special Government employees, shall obtain the prior written approval of an Agency Ethics Official before accepting compensated or uncompensated employment:

(i) As an officer, director, trustee, or general partner of, or in any other position of authority with, either a for-profit or non profit organization which directly or indirectly receives assistance from the Department.

(ii) With a State or local government; or

(iii) In the same professional field as that of the employee's official position.

(2) Approval shall be granted unless the conduct is inconsisent with 5 CFR part 2635 or this part.

(d) *Voluntary services.* Subject to the restrictions and requirements contained in the conflict of interest laws, 5 CFR part 2635, and this part, employees are encouraged to volunteer their personal time to nonprofit organizations.

Note to § 75.105: An employee assigned to serve in an official capacity as the Department's liaison representative to an outside organization is not engaged in an outside activity to which this section applies. Notwithstanding, an employee may be assigned to serve as the Department's liaison representative only as authorized by law, and as approved by the Department under applicable procedures.

§ 7501.106 Additional rules for certain Department employees involved in the regulation or oversight of Government sponsored enterprises.

(a) The following rules apply to certain Department employees whose duties involve the regulation or oversight of Government Sponsored Enterprises, specifically the Federal National Mortgage Association (FNMA) and the Federal Home Loan Mortgage Corporation (FHLMC). This section is in addition to §§ 7501.101 to 7501.105.

(b) *Definitions.* For purposes of this section, the following definitions are applicable:

(1) Except as provided in paragraph (b)(2) of this section, ''covered employee'' means all employees in the Office of Federal Housing Enterprise Oversight and employees required to file a public or confidential financial disclosure report under 5 CFR part 2634 in:

(i) The Office of the HUD Secretary, with the exception of the Office of Lead-Based Paint Abatement and Poisoning Prevention;

(ii) The Office of the Assistant Secretary for Housing—Federal Housing Commissioner;

(iii) The Office of Financial Institutions Regulation in the Office of the Assistant Secretary for Policy Development and Research;

(iv) The Offices of Investigation, Program Standards and Evaluation, and Regulatory Initiatives and Federal Coordination within the Office of the Assistant Secretary for Fair Housing and Equal Opportunity;

(v) The Office of General Counsel's Offices of Insured Housing, Government Sponsored Enterprises/Real Estate Settlement and Procedures Act Division in Finance and Regulatory Enforcement, Legislation and Regulations, and the Fair Housing Enforcement Division;

(vi) The Office of Inspector General;

(vii) The official superiors of the employees listed in paragraphs (b)(1)(iii), (b)(1)(iv) and (b)(1)(v) of this section;

(viii) Any other employee who is designated in writing by the Secretary, the Designated Agency Ethics Official, or the appropriate individual of Assistant Secretary rank, or his or her designee, to ensure compliance with the principles set forth in 5 CFR 2635.403 and who receives notice of such designation.

(2) The DAEO, upon recommendation of the appropriate individual of Assistant Secretary rank, may exclude in writing an employee otherwise designated as a ''covered employee'' under § 7501.106(b)(1)(i)–(vii) of this part if the employee's official duties do not substantially involve the regulation or oversight of Government sponsored enterprises and ownership of interests prohibited by § 7501.106(c) would not cause a reasonable person to question the impartiality and objectivity with which the Department's programs are administered.

(3) *Mortgage institution* means mortgage bankers, mortgage brokers, banks, savings and loans, and other institutions or entities that originate, insure, or service mortgages that are owned or guaranteed by the Federal National Mortgage Association (FNMA) or the Federal Home Loan Mortgage Corporation (FHLMC).

(c) *Prohibited financial interests.* (1) Except as provided in paragraph (c)(2) of this section, a covered employee, or a spouse or minor child of a covered employee, shall not receive, acquire, or own securities of:

(i) A mortgage institution if more than 20 percent of the institution's assets consist of mortgages;

(ii) A mortgage institution in which 20 percent or less of the institution's assets consist of mortgages and more than 40 percent of the mortgages originated by the institution are issued, collateralized, sold or guaranteed by FNMA and/or FHLMC; or

(iii) A mortgage institution which services or insures mortgages if more than 20 percent of the gross income of such institution is derived from either or both of these activities.

(2) The prohibitions in paragraph (c)(1) of this section do not apply to ownership of securities held in a publicly traded or publicly available investment fund, or profit-sharing, retirement, or similar plan which in its prospectus or governing documents does not indicate the objective or practice of concentrating its investments in the financial services sector, and the employee neither exercises control nor has the ability to exercise control over the financial interests held in the fund.

(3) The mortgage institution's most recent annual financial statement shall be used in determining the applicability of the prohibitions in paragraph (c)(1) of this section.

(d) *Restrictions arising from third party relationships.* If any of the entities listed below has securities that a covered employee would be prohibited from owning by paragraph (c) of this section, the employee shall report such

interest to the appropriate Agency Ethics Official. The Agency Ethics Official may require the employee to terminate the third party relationship, undertake an appropriate disqualification, or take other appropriate action determined to be necessary consistent with 5 CFR part 2635 and this part. This paragraph applies to a:

(1) Partnership in which the covered employee, or a spouse or minor child of the employee is a general partner;

(2) Partnership in which the covered employee, or spouse or minor child of the employee, individually or jointly holds more than a 10 percent limited partnership interest;

(3) Closely held corporation in which the covered employee, or spouse or minor child of the employee, individually or jointly holds more than a 10 percent equity interest;

(4) Trust in which the covered employee, or spouse or minor child of the employee, has a legal or beneficial interest;

(5) Investment club or similar informal investment arrangement between the covered employee, or spouse or minor child of the employee, and others; or

(6) Other entity in which the covered employee, or spouse or minor child of the employee, individually or jointly holds more than a 10 percent equity interest.

(e) *Prohibited outside employment.* Covered employees shall not engage in employment with or on behalf of the Federal National Mortgage Association, the Federal Home Loan Mortgage Corporation, a mortgage institution, or any of their affiliates.

(f) *Prohibited recommendations.* Covered employees shall not make any recommendation or suggestion, directly or indirectly, concerning the acquisition, sale, or divestiture of securities of FHLMC or FNMA.

(g) *Prohibited purchase of assets.* Covered employees, their spouses or minor children shall not purchase, directly or indirectly, any real or personal property from FHLMC or FNMA, unless it is sold at public auction or by other means which would assure that the selling price is the asset's fair market value.

(h) *Pre-existing interests.* Covered employees must report, in writing, to the appropriate Agency Ethics Official, any interest prohibited under paragraph (c) of this section acquired prior to either the commencement of employment as a covered employee or the effective date of this part, or acquired without specific intent, as through gift, inheritance, or marriage, within 30 days from the start of covered employment or acquisition of such interest. Such interest must be divested within 90 days from the date it is reported unless waived by the Designated Agency Ethics Official in accordance with § 7501.103.

TITLE 24—[AMENDED]

SUBTITLE A—OFFICE OF THE SECRETARY, DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

PART O—STANDARDS OF CONDUCT

2. In Part 0 of 24 CFR subtitle A, § 0.1 is revised to read as follows:

§ 0.1 Cross-reference to employees ethical conduct standards and financial disclosure regulations.

Employees of the Department of Housing and Urban Development (Department) are subject to the executive branch-wide standards of ethical conduct at 5 CFR part 2635, the Department's regulation at 5 CFR part 7501 which supplements the executive branch-wide standards, and the executive branch-wide financial disclosure regulation at 5 CFR part 2634.

Authority: 5 U.S.C. 301, 7301; 42 U.S.C. 3535(d).

[FR Doc. 96–17450 Filed 7–8–96; 8:45 am]
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July 9, 1996

Part VI

Department of Housing and Urban Development

Office of the Assistant Secretary for Community Planning and Development: Self-Help Homeownership Opportunity Program, Funding Availability and Guidelines; Notice

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4062–N–01]

Office of the Assistant Secretary for Community Planning and Development; Self-Help Homeownership Opportunity Program (SHOP) Notice of Funding Availability and Guidelines

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of funding availability for fiscal year 1996.

SUMMARY: This NOFA announces the availability of $15 million in funding for the Self-Help Homeownership Opportunity Program (SHOP), and contains information concerning basic program requirements, eligible applicants, funding available for grants, and application requirements and procedures. The NOFA is issued under section 11 of the Housing Opportunity Program Extension Act of 1996 (the ''Extension Act''). The program is being implemented through this NOFA and no application materials or forms are required other than as set out in this NOFA. No separate implementing regulations will be issued. Applicants are advised to consult section 11 of the Extension Act in order to prepare an application that is consistent with its requirements, some of which may not be repeated in this NOFA. Failure to follow the instructions and procedures contained in this NOFA or lack of adherence to the program requirements found in section 11 of the Extension Act will result in an application being rejected by HUD.

DATES: Completed applications for SHOP grants must be physically received by 4:30 p.m. Eastern Daylight Time on August 8, 1996. It is not sufficient for an application to bear a postmark within the deadline. *Applications sent by facsimile (FAX) will not be accepted.* HUD will not waive this deadline for actual submission for any reason. The application deadline is firm as to date and hour. In the interest of fairness to all competing applicants, the Department will treat as ineligible for consideration any application that is received after the deadline. Applicants should take this policy into account and consider early submission to avoid any risk of loss of eligibility brought about by any unanticipated or delivery-related problems.

ADDRESSES: An original and two copies of the completed application must be submitted to HUD Headquarters, Office of Community Planning and Development, Processing and Control Unit, Room 7251, 451 Seventh Street, SW, Washington, DC 20410, ATTN: Self-Help Program. (A 3.5≥ computer diskette containing the complete application may be substituted for one of the paper copies.)

FOR FURTHER INFORMATION CONTACT: Clifford Taffet, Office of Affordable Housing Programs, Department of Housing and Urban Development, room 7168, 451 Seventh Street, SW, Washington, DC 20410; telephone (202) 708–3226 EXT. 4589; (TTY (202) 708–2565). (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act Statement

The information collection requirements contained in this NOFA (FR–4062) have been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and 5 CFR 1320.13, and have been assigned OMB control number 2506–0157, expires September 30, 1996. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a valid control number.

This information collection is required in connection with the issuance of this NOFA, announcing the availability of $15 million for grants to encourage innovative homeownership opportunities through the provision of self-help housing where the homeowner contributes a significant amount of sweat equity toward construction of the dwellings. The information collection is needed so that HUD staff may determine the eligibility, qualifications and capability of applicants to carry out self-help and volunteer labor homeownership programs. HUD will review the information provided by the applicants against the selection criteria contained in the NOFA in order to rate and rank the applications and select the best and most qualified individual applications for funding. The selection criteria are: (1) Operational capability and experience; (2) financial capability and experience; (3) quality of program design; (4) leveraging of public/private resources; and (5) Empowerment Zone/Enterprise Community support.

The information is public information and is not subject to any confidentiality requirements other than the prohibition against advance information on funding decisions (see section III of this NOFA).

The estimates of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response are as follows:

	Number of respondents	Frequency of responses	Hours per response	Burden hours
Application Development	10	1	80	800
Total Estimated Burden Hours: 800				

The public is requested to send any comments concerning the accuracy of this burden estimate and any suggestions for reducing this burden to: Kay Weaver, Departmental Reports Liaison Officer, Office of Administration, Department of Housing & Urban Development, 451 7th Street, SW, Room 4176, Washington, DC 20410.

I. Purpose and Substantive Description

A. Authority

The funding made available under this NOFA is authorized by Section 11 of the Housing Opportunity Program Extension Act of 1996 (Pub. L. 104–120, 110 Stat 834, approved March 28, 1996). No separate implementing regulations will be issued. HUD may issue additional guidance containing more detailed policy than provided in this NOFA with respect to various aspects of the program, the management of funds, the environmental clearance process and similar matters, as necessary.

B. Purpose and Program Requirements

The Self-Help Homeownership Opportunity Program is intended to facilitate and encourage innovative homeownership opportunities through the provision of self-help housing where the homebuyer contributes a significant amount of sweat-equity toward the construction of the new dwelling. This

program will increase homeownership levels and is in furtherance of the National Homeownership Strategy. The strategy is a five-year blueprint for cooperative actions identified by 56 private and public organizations that is intended to achieve an all-time high level of homeownership by the year 2000. The National Homeownership Strategy, ''Partners in the American Dream'' was prepared by the Department and its Partners in response to a request from President Clinton in 1995. These decent, safe, and sanitary nonluxury dwellings must be made available to eligible homebuyers at prices below the prevailing market prices. Eligible homebuyers are low-income families (families whose annual incomes do not exceed 80 percent of the median income for the area, as determined by HUD) who are unable to otherwise afford to purchase a dwelling. Activities to develop housing assisted under this NOFA must involve community participation, by providing for the utilization of volunteers in the construction of dwellings or by other activities designed to involve the community in the project. The only eligible expenses for program funds are land acquisition (including financing and closing costs) and infrastructure improvement (installing, extending, constructing, rehabilitating, or otherwise improving utilities and other infrastructure). Administrative expenses and costs associated with the rehabilitation, improvement, or construction of dwellings are not eligible uses of program funds. Among the program requirements contained in section 11 of the Extension Act that the applicant's proposed program design must meet in order to be considered as eligible are the following: (1) to provide for development, through significant amounts of sweat-equity and volunteer labor, of at least 30 dwellings at an average cost of no more than $10,000 per unit in SHOP funds; (2) to use the grant in a manner that leverages other sources of funding, including private or other public funds; (3) to construct quality dwellings that comply with local building and safety codes and standards and are available at prices below the prevailing market price; and (4) to schedule activities so as to substantially fulfill the obligations under the grant agreement within 24 months after grant amounts are first made available to the organization or consortia. HUD will recapture undisbursed amounts from the grantees who fail to substantially fulfill these obligations within 24 months.

C. Other Federal Requirements

Grantees awarded funds under this NOFA are subject to the following requirements: The administrative requirements of 24 CFR part 84, OMB Circular A–122 and the audit requirements in 24 CFR part 45 (implementing OMB Circular A–133); the Equal Opportunity requirements referred to in 24 CFR 5.105(a) (61 FR 5198, 5202, published February 9, 1996); the provisions contained in Section 305 of the Multifamily Housing Property Disposition Reform Act of 1994, Environmental Review, codified in the Environmental Review regulations at 24 CFR part 58, are applicable to properties assisted with SHOP funds (see next paragraph); the requirements of the Uniform Relocation Act, as implemented by 49 CFR part 24; the lead-based paint requirements set out in 24 CFR part 35; the requirements of section 3 of the Housing and Urban Development Act of 1968 concerning infrastructure improvements funded with SHOP funds; restrictions on participation by ineligible, debarred or suspended persons or entities referred to in 24 CFR 5.105(c); and the Drug-Free Workplace authorities referred to in 24 CFR part 24.

Use of SHOP funds is subject to the environmental review requirements that apply to HUD Special Projects in accordance with Section 305(c) of the Multifamily Housing Property Disposition Reform Act of 1994, as implemented in 24 CFR part 58 (final rule published on April 30, 1996, 61 FR 19120, effective May 30, 1996). Recipients are cautioned that they may not commit either SHOP or non-HUD funds for most activities until a Federal environmental review is performed by a unit of general local government, tribe or State, and until HUD approves a recipient's request for release of funds under part 58.

D. Allocation Amounts

This NOFA makes available $15 million in SHOP grants, in accordance with sections 11(c)(2) and 12(b)(1) of the Housing Opportunity Program Extension Act of 1996.

E. Unused Funds

If funds remain after HUD has approved all approvable grant applications, the excess will be provided to Habitat for Humanity International for use in accordance with the requirements of section 11 of the Extension Act.

F. Eligible Applicants

Except as noted below, eligible applicants are nonprofit national or regional organizations or consortia that have experience in providing or facilitating self-help housing homeownership opportunities, and that have standards of financial accountability that conform to 24 CFR 84.21, ''Standards for Financial Management Systems''. Applicants receiving awards are required to have audits conducted in accordance with the provisions of 24 CFR part 45 (OMB Circular A–133) or a program-specific financial audit, as appropriate. Where the applicant is a consortium, one organization must be chosen as the lead applicant. The lead applicant will execute the application documents and, if the application is selected for funding, will execute the grant agreement and assume primary responsibility for carrying out the grant activities in compliance with all program requirements. Other participants in the consortium should be listed in the narrative section of the application addressing rating criteria numbers (1) (''Operational Capability and Experience of the Applicant''); and (2) (''Financial Capability and Experience of the Applicant''). Affiliates of Habitat for Humanity International are not eligible for funding under this NOFA since SHOP funds are being made available to them separately under section 11 of the Extension Act.

II. Grant Applications

A. Application Submission

Only timely applications received at HUD Headquarters will be considered for funding (see ''Addresses'' at the beginning of this NOFA). Applications (original and two copies) must be physically received no later than 4:30 p.m. Eastern Daylight Time on the deadline (see ''Dates'' at the beginning of this NOFA). It is not sufficient for an application to bear a postmark within the deadline. Applications sent by facsimile (FAX) will not be accepted.

B. Application Requirements

All applicants must submit applications on 8½″ by 11″ paper which are bound in loose leaf binders for easy copying. All pages and attachments must be numbered consecutively. Applications must contain the following items: (1) OMB *Standard Form 424,* Request for Federal Assistance, *Standard Form 424B,* Non-Construction Assurances, *Certification Concerning Use of Federal Funds for Lobbying,* and *Certification Concerning Drug-Free Workplace* signed by a person legally authorized to enter into an agreement with HUD; and (2) a detailed narrative statement and program

description which addresses each of the five Rating Criteria in Section II.E of this NOFA. Requests for copies of the standard forms and certifications can be made by calling Community Connections at 1–800–998–9999 or by fax to HUD, ATTN: Cliff Taffet, at (202) 708–1744. (This is not a toll-free number.) Please refer to the ''Self-Help Program'' in your request. The application will become part of the grant agreement to be entered into by successful applicants.

C. Selection Process

The selection process for grants under SHOP consists of a screening review, and then, for those applications meeting all screening requirements, rating and ranking under substantive rating criteria. However, rating and ranking will only occur if there are more funds requested in applications that meet screening requirements than are available under this NOFA.

D. Screening Process/Corrections to Deficient Applications

(1) HUD will screen each application submitted on or before the deadline to determine if it is complete, is internally consistent, contains correct computations, and complies with all requirements of section 11 of the Extension Act and this NOFA.

(2) Where HUD determines that an application as initially submitted is fundamentally incomplete or would require substantial revisions, it will not consider the application further.

(3) Where HUD determines an application is deficient in one or more of the areas in paragraph D(1) of this section but is not fundamentally incomplete and does not require substantial revisions, it will notify the applicant in writing and give it an opportunity to correct the technical deficiencies that do not pertain to the merits of its submission. HUD will not notify the applicant of any deficiencies in material that is to be evaluated under the rating criteria.

(4) The notification will require the applicant to submit additional or corrected items so that they are received in HUD Headquarters by no later than 4:30 p.m. Eastern Daylight Time on the 14th calendar day after the date of the written notification to the applicant giving it an opportunity to correct the deficiency. HUD may not extend this deadline for actual receipt of the material for any reason. After review of all additional or corrected materials, HUD will not consider further any applications that do not comply with the requirements of the NOFA and section 11 of the Extension Act.

E. Rating Criteria

All applications meeting the screening requirements in section D will be rated and ranked, using the following substantive rating criteria:

(1) Operational Capability and Experience of the Applicant—(up to 30 points). The applicant will be rated on its ability to develop and carry out the proposed program in a reasonable time and successful manner. In assigning points for this criterion, HUD will consider evidence demonstrating previous experience of the applicant, the participating members of consortia, other co-applicants and the key staff of these organizations in managing self-help housing and volunteer labor projects involving acquisition, construction, real estate financing, counseling and training or other relevant activities. The applicant must identify in its application the key staff who will be responsible for implementing the program and describe their qualifications. In addition, the applicant must provide, as evidence of its nonprofit status, a copy of a current Internal Revenue Service ruling that the applicant is exempt from taxation under section 501(c)(3) or 501(c)(4) of the Internal Revenue Code of 1986. Where an IRS ruling is unavailable, an applicant may submit a certified copy of its approved charter, articles of incorporation or bylaws, demonstrating that the applicant is established as a nonprofit organization under state law. Where the applicant is a consortium, each participant in the consortium must be a nonprofit organization, but only the lead applicant should submit evidence of its nonprofit status. However, the lead applicant must maintain a copy of the above-described documentation for each participant in the consortium.

(2) Financial Capability and Experience of the Applicant—(up to 20 points). The applicant will be rated on its capability to handle financial resources and follow procedures for effective control. In assigning points for this criterion, HUD will consider evidence demonstrating previous experience of the applicant, the participating members of consortia, other co-applicants, and the key staff of these organizations, and the adequacy of existing financial control procedures. Applicants must include in their narrative statement a description of the financial control system, and provide supporting documentation, including a copy of their most recent audit.

(3) Quality of Program Design—(up to 30 points). In assigning points for this criterion, HUD will consider the extent to which the proposed program is complete, feasible, innovative, geographically diverse, and likely to substantially fulfill the obligations of the applicant under the program within 24 months. Applicants must include in their narrative a program schedule and performance benchmarks for the initial 24 month period of the grant agreement (including the number of units to be developed and occupied) that constitute substantial fulfillment of programmatic obligations. The applicant must also present a budget which includes the sources and uses of all funds, including program income and accrued interest, and provide a description of the applicant's cash management system and proposed distribution of funds among participating organizations. The program design narrative must be detailed and describe other aspects of the program including, but not limited to: the administrative structure and program monitoring; the procedures to be followed in selecting properties, meeting environmental review requirements, and choosing homebuyers; the sweat-equity and community participation volunteer requirements; the size and design of the new dwellings, including features to allow entrance and passage through the house by people who use wheelchairs and to promote energy efficiency; the use of cost reducing innovations in construction technologies and land planning; the counseling and training components; the terms of sale to homebuyers; and the identification of participating lenders. This section of the application should contain sufficient information to determine that the applicant understands and intends to comply with other requirements of the Extension Act and the NOFA, such as the requirements that the homes developed will be sold to eligible homebuyers at prices below prevailing market prices, and that all local building and safety codes and standards will be complied with.

(4) Leveraging of Public/Private Resources—(up to 20 points). In assigning points for this criterion, HUD will consider the extent and firmness of commitments by the public and private sector in support of the program, such as the donation of labor or materials, interest rate reductions or other financing subsidies, volunteer assistance, tax abatements, public works improvements, waivers of fees or taxes, expedited processing of permits and applications, removal of regulatory barriers to affordable housing, and supportive services (including counseling and training). Applicants should provide letters or other

documentation evidencing the extent and firmness of these commitments.

(5) Empowerment Zone/Enterprise Community Support—(up to 5 points). In assigning points for this criterion, HUD will consider the extent to which the applicant's program design provides for the selection of sites for development located in Federally designated urban or rural Empowerment Zones, Enterprise Communities or Supplemental Empowerment Zones, as selected by the Secretaries of HUD and USDA.

Rating of the ''applicant'' or the ''applicant's organization and staff'' will include any members of the national and regional organization or consortium participating in the application. Irrespective of final scores, HUD may make selections out of rank order to achieve a national geographic diversity. Additionally, HUD reserves the right to reduce the amount of funding for an application below that which was requested.

F. Ranking and Selection

After assigning points under the selection criteria, HUD shall examine the rankings and, where it determines that applications falling below a certain point total are not suitable or not feasible for funding, it may establish a minimum number of points for applications to qualify to be selected for funding. HUD shall select for funding in rank order all fundable applications, if any. Once these selections have been made (within 6 months of the publication of this NOFA), HUD will provide excess funds remaining from the $15 million allocation to Habitat for Humanity International to be used as provided for under section 11 of the Extension Act.

III. Other Matters

Environmental Impact

A Finding of No Significant Impact with respect to the environment has been made for the program in accordance with HUD regulations at 24 CFR part 50, which implements section 102(2)(C) of the National Environmental Policy Act of 1969. The Finding is available for public inspection between 7:30 a.m. and 5:30 p.m. weekdays in the Office of the Rules Docket Clerk, Office of the General Counsel, Department of Housing and Urban Development, room 10276, 451 Seventh Street, SW, Washington, DC 20410.

Federalism Executive Order

The General Counsel, as the Designated Official for HUD under section 6(a) of Executive Order 12612, Federalism, has determined that the provisions in this NOFA are closely based on statutory requirements and impose no significant additional burdens on States or other public bodies. This NOFA does not affect the relationship between the Federal Government and the States and other public bodies or the distribution of power and responsibilities among various levels of government. Therefore, the policy is not subject to review under Executive Order 12612.

Family Executive Order

The General Counsel, as the Designated Official under Executive Order 12606, The Family, has also determined that some of the policies in this NOFA will have a potential significant impact on the formation, maintenance, and general well-being of the family. Achievement of homeownership by low-income families in the program can be expected to support family values, by helping families achieve security and independence; by enabling them to live in decent, safe and sanitary housing; and by giving them the skills and means to live independently in mainstream American society. Since the impact on the family is beneficial, no further review is necessary.

Section 102 of the HUD Reform Act—Accountability in the Provision of HUD Assistance

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) in HUD's implementing regulations at 24 CFR part 15. In addition, HUD will publish a Federal Register notice of all recipients awarded assistance under this NOFA. (See 24 CFR part 4, subpart A (61 FR 14448, 14449 published April 1, 1996).)

Section 103 of the HUD Reform Act—Prohibition against Advance Information on Funding Decisions.

HUD's regulation implementing section 103 of the Department of Housing and Urban Development's Reform Act of 1989, codified as 24 CFR part 4, applies to the funding competition announced today. The requirements of the rule continue to apply until the announcement of the selection of successful applicants. HUD employees involved in the review of applications and in the making of funding decisions are limited by 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 under 24 CFR part 4, subpart B (61 FR 14448, 14451, published April 1, 1996).

Applicants or employees who have ethics related questions should contact the HUD Office of Ethics (202) 708–3815. (This is not a toll-free number.) For HUD employees who have specific program questions, such as whether particular subject matter can be discussed with persons outside HUD, the employee should contact the appropriate Field Office Counsel or Headquarters Counsel for the program to which the question pertains.

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) (''Byrd Amendment'') 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.

Dated: June 27, 1996.

Henry G. Cisneros,

Secretary.

[FR Doc. 96–17373 Filed 7–8–96; 8:45 am]

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Federal Register

Tuesday
July 9, 1996

Part VII

Department of Housing and Urban Development

24 CFR Part 200, et al.

Single Family Miscellaneous Amendments, Clarifications, and Corrections; Final Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 200, 201, 202, 203, 206, 221, 233, 234, 280 and 291

[Docket No. FR–3977–F–01]

RIN 2501–AG61

Office of the Assistant Secretary for Housing-Federal Housing Commissioner; Single Family Miscellaneous Amendments, Clarifications, and Corrections

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

ACTION: Final rule.

SUMMARY: This final rule makes a variety of technical amendments, clarifications and corrections to regulations for the single family mortgage insurance programs. None of the amendments or clarifications add to the regulatory burden for mortgagors or mortgagees.

EFFECTIVE DATE: August 8, 1996.

FOR FURTHER INFORMATION CONTACT: John J. Coonts, Director, Office of Insured Single Family Housing, Department of Housing and Urban Development, Room 9266, 451 Seventh Street, SW, Washington, DC 20410. Telephone: (202) 708–3046; TTY: (202) 4594. (These are not toll-free telephone numbers.)

SUPPLEMENTARY INFORMATION: This rule is designed to make a large number of technical improvements to the regulations for single family programs. The changes will not add to the regulatory burden for mortgagors or mortgagees. Some of the changes are corrections of small errors in the current regulations that will have no substantive change on the way the rules have been applied in practice. Other changes will offer relief from unnecessary requirements.

Following is an explanation of changes made by the rule.

Part 200

A technical change is made to part 200 to remove a reference to part 267 which has been removed from the Code of Federal Regulations.

Part 201

The rule makes a typographical correction to the table of contents and to § 201.18.

Part 202

Section 202.3 is amended to revise paragraph (j) to provide that the Secretary may identify classes or groups of lenders that are exempt from one or more of these fees. This provides more flexibility to the program by allowing additional groups to be exempted.

''Origination approval agreement'' is included in the heading of § 202.11.

The rule deletes § 202.12(d). That paragraph indicates that approval of a supervised mortgagee that is a banking institution or a trust company included approval of the mortgagee when acting in a fiduciary capacity. The Department considers that the paragraph may be misleading by implying that only supervised mortgagees that are banking institutions or trust companies may hold mortgages in a trust or other fiduciary capacity. Subject to any limitations that may appear in regulations for particular programs, such as § 203.434, regarding a declaration of trust for a pool of single family mortgages, the Department does not restrict mortgagees from holding mortgages in a trust or other fiduciary capacity. The Department eliminated trusts as eligible mortgagees through a 1992 revision of part 202 but there was no intent to prevent FHA-insured mortgages from being held as trust assets by an approved mortgagee. The Department will deal only with the mortgagee, rather than others who may have interests in the mortgages, and will hold the mortgagee solely responsible for complying with obligations imposed on mortgagees.

The provisions regarding approval and recertification fees for Title I lenders and Title II mortgagees are amended by adding a new sentence permitting the Secretary to identify classes or groups of lenders or mortgagees that are exempt from one or more of the fees. The current exemption for governmental lenders and mortgagees is left intact.

Part 203

The rule eliminates the requirement in § 203.17(b) (and corresponding requirements in §§ 221.45 and 234.25(b)) that mortgages involve a principal obligation in multiples of $50 if the mortgage does not include financing of a one-time mortgage insurance premium (MIP) payable pursuant to § 203.280. One time MIP has been replaced by the up-front segment of risk-based mortgage insurance premiums under §§ 203.284 and 203.285. Rather than substitute the up-front segment of risk-based MIP for the one time MIP, however, the Department has determined that there is no longer any reason for the general requirement that other mortgages without a financed premium be in multiples of $50. All mortgages may now be in multiples of $1. Corresponding changes are made to §§ 221.45 and 234.52.

Two changes are made to § 203.18 which explain how the maximum mortgage amount is calculated. A parenthetical phrase is removed from § 203.18(a)(1)(ii) to reflect the 1994 legislative change that set the maximum dollar amount for an area at 75% of the *current* Freddie Mac limit, instead of 75% of the *1992* Freddie Mac limit. A new § 203.18(i) is added to recognize that the maximum mortgage amount for an energy efficient mortgage may exceed the area dollar limit that would otherwise apply, under conditions prescribed by the Secretary in accordance with section 106 of the Energy Policy Act of 1992.

Section 203.19(c) which applied to the now-repealed section 203(m) program for mortgage insurance for seasonal homes is deleted as obsolete.

Language is added in § 203.22(a) to clarify that the mortgage provision providing for payment of mortgage insurance premium installments by the mortgagor does not require payment for any longer than the period during which mortgage insurance premiums are payable by the mortgagee to HUD. Obsolete language regarding payment of annual charges on ''open-end'' advances is deleted.

Sections 203.24(a)(i) and 203.44, and related provisions in other parts such as 234.70, are amended by deleting references to open-end advances.

Section 203.30 is amended to add a new paragraph (d) regarding compliance, for buildings having four (4) or more units which were built for first occupancy after March 13, 1991, with the Fair Housing Act new contruction requirements at 24 CFR 100.205.

Sections 203.36 and 234.67 are deleted as unnecessary. See sections 203.16 and 234.15 regarding the use of a dwelling for transient or hotel purposes.

The language in section 203.38 is amended by changing the two references to ''unit'' to ''one or more dwellings.''

In §§ 203.40, 203.251(s), and 234.1(n), ''Commonwealth of the Northern Mariana Islands'' is substituted for the ''Trust Territory of the Pacific Islands'' because the Commonwealth of the Northern Mariana Islands is the only portion of the former Trust Territory of the Pacific Islands in which FHA single family programs are currently authorized.

The ''rule of seven'' in § 203.42 currently prohibits mortgage insurance when a mortgagor is purchasing a property to be rented that is ''part of, or adjacent or contiguous to, a project, subdivision or group of similar rental

properties'' in which the mortgagor will have a financial interest in more than seven dwelling units. This rule removes ''subdivision'' from the quoted language. Denial of mortgage insurance simply because a mortgagor has a financial interest in eight units in a very large subdivision does not further the purpose of the ''rule of seven,'' which is to avoid insuring single family mortgages on rental units that are in such close geographical proximity with other similar rental units that they could logically be considered part of one multifamily project rather than unrelated single family units. In practice, current departmental policy in applying the ''rule of seven'' has been directed to properties within a two-block radius from one another. Continued reference to a subdivision would cause confusion regarding the intent of § 203.42.

Section 203.43(c)(3) and the corresponding § 234.52(c) are amended to permit a $50 increase in the monthly payment for refinancing to a shorter term, to reflect the prevailing policy that has been applied to date on a waiver basis.

Section 203.43b regarding mortgage insurance on seasonal occupancy homes under now-repealed section 203(m) is deleted as obsolete.

Section 203.43f(b) is amended by deleting the last sentence which refers to section 203.17(e). Section 203.17(e) was completely revised and the current cross-reference is not meaningful.

The introductory paragraph of § 203.43h is revised to clarify that a mortgage covering a one- to four-family residence located on Indian land is eligible for insurance pursuant to section 248 of the National Housing Act, if the mortgage is made (1) by an Indian Tribe or (2) on a leasehold estate, by an Indian who will occupy it as a principal residence. Tribes are already recognized as eligible non-occupant mortgagors under § 203.18(f)(3). This amendment to § 203.43h reconciles the two sections. In addition, a statement has been added to the definition of an ''Indian tribe,'' in § 203.43h(g), to note that, for purposes of engaging in section 248 insured mortgage transactions, an Indian tribe may act through its duly authorized representative.

The reference to § 203.50 contained in § 203.43i is deleted to allow rehabilitation loan mortgages under section 203(k) on section 247 Hawaiian home lands. This would have been permitted by a proposed rule published on July 23, 1986, but the provision was omitted from a final rule on the Hawaiian home lands program published on March 16, 1987, because of the difficulty of operating the Hawaiian home lands program for the General Insurance Fund (as required for section 203(k) loans) in addition to the Mutual Mortgage Fund. This difficulty no longer exists as a result of a subsequent statutory change that provides for all Hawaiian home land mortgages to be in the General Insurance Fund.

Section 225 of the National Housing Act authorizes FHA insurance for open-end mortgages under which the mortgagee could advance additional funds under the mortgage to finance later improvements or repairs that would substantially protect or improve the basic livability or utility of the property. Although mentioned in the regulations, FHA does not have administrative procedures for the processing of open-end mortgages; they are not provided for in HUD's instructions for mortgage forms, and GNMA has no programs for the pooling of open-end mortgages. Various provisions in parts 203 and 234, including §§ 203.44 and 234.70, are amended to make clear that FHA is not insuring open-end mortgages.

The introductory paragraph of § 203.49 is amended by including a reference to section 203(h) in the second sentence to permit adjustable rate mortgages (ARMs) in disaster situations. Section 203(h) mortgages generally meet all requirements of section 203(b) mortgages except that a higher loan-to-value ratio is permitted. The Department has determined that ARMs should be available on the same terms as for section 203(b) mortgages.

Some issuers of 10-year warranty plans that have been approved by HUD and used to support high-ratio mortgages for new construction have read HUD's warranty plan requirements as permitting plans that impose the requirement that homeowners submit warranty claims to arbitration. This has never been HUD's intention under the warranty plan final rule. Although arbitration must be available to a dissatisfied homeowner, judicial resolution of disputes must also be available to homeowners. HUD has modified the wording of § 203.204(g) to make this clear.

Section 203.255(b)(2) is amended by replacing ''upon a form'' with ''in a form'' since application information may now be collected electronically through CHUMS.

Section 203.281(b)(1) is amended by deleting the language following the first comma to simplify the procedures for calculating the MIP amount for the small number of cases for which one-time MIP is still used.

Sections 203.356 and 203.402 regarding the notice of foreclosure are amended to provide a more consistent application of the rules for curtailment of debenture interest included in insurance benefits paid to mortgagees. Section 203.356 is divided into subsection (a) for the requirements to provide the notice of foreclosure, and subsection (b) for exercising reasonable diligence in prosecuting the foreclosure. Section 203.402(k)(1) is also subdivided. New subsection 203.402(k)(1)(ii) limits the amount of debenture interest that the Secretary may curtail if the mortgagee does not provide the Secretary the notice of foreclosure. This change will reduce the debenture interest curtailment when the mortgagee proceeded to foreclose with reasonable diligence, despite its failure to forward the initial notice of foreclosure. The specific cap on debenture interest curtailment will be set by administrative issuances, but the curtailment will not exceed what is currently being assessed.

Sections 203.378, 203.379, and 203.380 regarding property condition and adjustments for damage are amended to clarify that tornado damage includes damage by hurricanes. Both storm systems are defined as violent whirlwinds and historically have been treated the same by the Department in this regard.

Section 203.502(b) regarding notification of transfer of servicing is amended to change the responsibility for notifying the Secretary from the transferor mortgagee to the transferee. This change will enhance HUD's ability to coordinate the change in servicer with the collection of mortgage insurance premiums from the new servicer.

Section 203.670 addresses conveyance of occupied property. Paragraph (a) states HUD's property disposition policy, which is also stated in § 291.1 in part 291, Disposition of HUD-Acquired Single Family Property. However, § 291.1 was amended to reflect a revised policy in a September 20, 1993 Interim Rule, made final on September 22, 1994. Therefore, § 203.670(a) is being amended to reflect the revised policy.

Section 203.685 is removed. It authorized waivers of single family servicing regulations, but such waivers are now authorized by the Department-wide waiver authority in 24 CFR 5.100.

Part 206

Section 206.13 is removed because it addresses the terminated single family co-insurance program. Section 206.17 is amended to recognize that the basic payment term and tenure payment

options for HECMs can be combined with lines of credit.

Part 234

Sections 234.11 and 234.54 are added to conform to corresponding provisions in part 203.

Section 234.16 is amended to add a new paragraph (d) regarding compliance, for buildings having four (4) or more units which were built for first occupancy after March 13, 1991, with the Fair Housing Act new construction requirements at 24 CFR 100.205.

Part 280

Section 280.330(c)(2) is amended by adding the following language: ''. . . remaining balance of the . . .''. The way this section is currently written, it appears that the entire original mortgage amount is cancelled. In addition, the spelling of ''cancelled'' is corrected.

Part 291

Section 291.105(h)(2) is amended to give the Secretary more flexibility in determining what form of cash equivalents will be acceptable for earnest money deposits in the sale of HUD-acquired single family properties, given rapidly changing banking industry practices. For example, the amendment permits HUD to accept teller's checks that are currently excluded.

Section 291.115(b)(2) of the regulations on HUD property disposition is amended to clarify that section 203(k) insured financing for investors is available for eligible properties without increased down-payment requirements. Section 291.110(e) already provides for section 203(k) financing in property disposition sales. As a general rule, investors are precluded from obtaining FHA-insured mortgage financing. HUD-acquired properties may be sold to investors with FHA-insured financing but, in order to protect the insurance funds, based upon past experiences, the property disposition regulations were drafted to require higher down-payments for investors. A 25 percent down-payment is required for investors who purchase a one-unit single family dwelling with insured mortgage financing.

The section 203(k) program specifically makes investors eligible to obtain mortgage financing with a 15 percent down-payment based upon the lesser of the estimated value of the property plus the cost of rehabilitation, or 110 percent of the estimate of value after rehabilitation. The availability of the section 203(k) program for property disposition sales, as provided by § 291.110(e), incorporates the 15 percent down-payment requirement for investors through the regulations that implement section 203(k). In order to make it clear that the 25 percent down-payment provision of § 291.115(b)(2) does not apply to section 203(k) investor mortgages, a technical amendment is being made to that section.

Typographical and Technical Errors, and Cross Reference Corrections

This rule corrects several typographical and technical errors and also corrects and adds cross references and removes cross references that are no longer applicable. Also, § 203.390 is amended to insert language inadvertently omitted when that section was last amended on July 1, 1993, at 58 FR 35369.

Other Matters

Justification for Final Rulemaking

In general, the Department publishes a rule for public comment before issuing a rule for effect, in accordance with its own regulations on rulemaking, 24 CFR part 10. However, part 10 does provide for exceptions from that general rule where the agency finds good cause to omit advance notice and public participation. The good cause requirement is satisfied when prior public procedure is ''impracticable, unnecessary, or contrary to the public interest.'' (24 CFR 10.1) The Department finds that good cause exists to publish this rule for effect without first soliciting public comment, in that prior public procedure is unnecessary and contrary to public interest because the amendments made by this rule give greater clarity and accuracy to the provisions. They do not substantively affect the rights and duties of participants in the programs.

Environmental Impact

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50, which implements section 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA). This Finding of No Significant Impact is available for public inspection between 7:30 a.m. and 5:30 p.m. weekdays in the Office of the Rules Docket Clerk, Office of the General Counsel, Department of Housing and Urban Development Room 10276, 451 Seventh Street, SW, Washington, DC 20410.

Regulatory Flexibility Act

The Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this rule before publication and by approving it certifies that this rule does not have a significant economic impact on a substantial number of small entities. This final rule makes a variety of technical amendments, clarifications and corrections to regulations for the single family mortgage insurance programs. None of the amendments or clarifications add to the regulatory burden for mortgagors or mortgagees.

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 will not have substantial direct effects on states or their political subdivisions, or the relationship between the federal government and the states, or on the distribution of power and responsibilities among the various levels of government. As a result, the rule is not subject to review under the order.

Executive Order 12606, The Family

The General Counsel, as the Designated Official under Executive Order 12606, *The Family*, has determined that this 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. No significant change in existing HUD policies or programs will result from promulgation of this rule, as those policies and programs relate to family concerns.

List of Subjects

24 CFR Part 200

Administrative practice and procedure, Claims, Equal employment opportunity, Fair housing, Home improvement, Housing standards, Incorporation by reference, Lead poisoning, Loan programs—housing and community development, Minimum property standards, Mortgage insurance, Organization and functions (Government agencies), Penalties, Reporting and recordkeeping requirements, Social security, Unemployment compensation, Wages.

24 CFR Part 201

Health facilities, Historic preservation, Home improvement, Loan programs—housing and community development, Manufactured homes, Mortgage insurance, Reporting and recordkeeping requirements.

24 CFR Part 202

Administrative practice and procedure, Home improvement, Manufactured homes, Mortgage

insurance, Reporting and recordkeeping requirements.

24 CFR Part 203

Hawaiian Natives, Home improvement, Indians—lands, Loan programs—housing and community development, Mortgage insurance, Reporting and recordkeeping requirements, Solar energy.

24 CFR Part 206

Aged, Condominiums, Loan programs—housing and community development, Mortgage insurance, Reporting and recordkeeping requirements.

24 CFR Part 221

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

24 CFR Part 233

Home improvement, Loan programs—housing and community development, Mortgage insurance, Reporting and recordkeeping requirements.

24 CFR Part 234

Condominiums, Mortgage insurance, Reporting and recordkeeping requirements.

24 CFR Part 280

Community development, Grant programs—housing and community development, Loan programs—housing and community development, Low and moderate income housing, Nonprofit organizations, Reporting and recordkeeping requirements.

24 CFR Part 291

Community facilities, Conflict of interests, Homeless, Lead poisoning, Low and moderate income housing, Mortgages, Reporting and recordkeeping requirements, Surplus government property.

Accordingly, in title 24 of the Code of Federal Regulations, parts 200, 201, 202, 203, 206, 221, 233, 234, 280, and 291 are amended as follows:

PART 200—INTRODUCTION

1. The authority citation for 24 CFR part 200 continues to read as follows:

Authority: 12 U.S.C. 1701–1715z–18; 42 U.S.C. 3535(d).

§ 200.810 [Amended]

2. Section 200.810(b) is amended to remove the phrase ‘‘, who shall be listed on the HUD Appraiser Roster under § 267.8(d)(2) of the chapter,’’.

PART 201—TITLE I PROPERTY IMPROVEMENT AND MANUFACTURED HOME LOANS

3. The authority citation for 24 CFR part 201 continues to read as follows:

Authority: 12 U.S.C. 1703; 42 U.S.C. 1436a and 3535(d).

§ 201.18 [Amended]

4. Section 201.18 is amended by revising the section heading to read, ‘‘Modification agreement or repayment plan.’’

PART 202—APPROVAL OF LENDING INSTITUTIONS AND MORTGAGEES

5. The authority citation for 24 CFR part 202 continues to read as follows:

Authority: 12 U.S.C. 1703, 1709, and 1715b; 42 U.S.C. 3535(d).

6. Section 202.3(j) is amended to add at the end the following sentence:

§ 202.3 General approval requirements.

* * * * *

(j) * * * The Secretary may identify classes or groups of lenders that are exempt from one or more of these fees.

* * * * *

7. Section 202.11 is amended by revising the section heading to read as follows:

§ 202.11 Approval, origination approval agreement, recertification, withdrawal of approval and termination of approval agreement.

* * * * *

8. Section 202.12(k) is amended to add at the end the following sentence:

§ 202.12 General approval requirements.

* * * * *

(k) * * * The Secretary may identify classes or groups of mortgagees that are exempt from one or more of these fees.

* * * * *

§ 202.13 [Amended]

9. Section 202.13 is amended by removing paragraph (d) and redesignating paragraph (e) as paragraph (d).

PART 203—SINGLE FAMILY MORTGAGE INSURANCE

10. The authority citation for 24 CFR part 203 continues to read as follows:

Authority: 12 U.S.C. 1709, 1710, 1715b, and 1715u; 42 U.S.C. 3535(d).

11. Section 203.5 is amended by revising paragraph (e) to read as follows:

§ 203.5 Direct Endorsement process.

* * * * *

(e) *Appraisal.* (1) A mortgagee shall have the property appraised in accordance with such standards and requirements as the Secretary may prescribe.

(2) The mortgagee shall not discriminate on the basis of race, color, religion, national origin, sex, age, or disability in the selection of an appraiser.

12. Section 203.17 is amended by revising paragraph (b) to read as follows:

§ 203.17 Mortgage provisions.

* * * * *

(b) *Mortgage multiples.* A mortgage shall involve a principal obligation in a multiple of $1.

* * * * *

13. Section 203.18 is amended to remove the parenthetical phrase ‘‘(as in effect on September 30, 1992)’’ in paragraph (a)(1)(ii) and to add a new paragraph (i) to read as follows:

§ 203.18 Maximum mortgage amounts.

* * * * *

(i) *Energy efficient mortgages.* The principal amount of energy efficient mortgages may exceed the maximum amounts determined under paragraph (a)(1) of this section under conditions prescribed by the Secretary in accordance with section 106 of the Energy Policy Act of 1992.

§ 203.19 [Amended]

§ 203.19 [Amended]

14. Section 203.19 is amended by removing paragraph (c).

15. Section 203.22 is amended by revising paragraph (a) to read as follows:

§ 203.22 Payment of insurance premiums or charges; prepayment privileges.

(a) *Payment of periodic insurance premiums or charges.* Except with respect to mortgages for which a one-time mortgage insurance premium is paid pursuant to § 203.280, the mortgage may provide for monthly payments by the mortgagor to the mortgagee of an amount equal to one-twelfth of the annual mortgage insurance premium payable by the mortgagee to the Commissioner. Such payments continue only so long as the contract of insurance shall remain in effect or for such shorter period as mortgage insurance premiums are payable by the mortgagee to the Commissioner.

* * * * *

16. Section 203.24 is amended by revising paragraph (a)(1) to read as follows:

§ 203.24 Application of payments.

(a) * * *

(1) Premium charges under the contract of insurance (other than a one-time or up-front mortgage insurance

premium paid in accordance with §§ 203.280, 203.284 and 203.285), charges for ground rents, taxes, special assessments, flood insurance premiums, if required, and fire and other hazard insurance premiums;

* * * * *

17. Section 203.30 is amended by adding a new paragraph (d) to read as follows:

§ 203.30 Certificate of nondiscrimination by the mortgagor.

* * * * *

(d) That buildings having four (4) or more units, which were built for first occupancy after March 13, 1991, were constructed in compliance with the Fair Housing Act new construction requirements in 24 CFR 100.205.

§ 203.36 [Removed and reserved]

18. Section 203.36 is removed and reserved.

19. Section 203.38 is revised to read as follows:

§ 203.38 Location of dwelling.

At the time a mortgage is insured there must be located on the mortgaged property one or more dwellings designed principally for residential use for not more than four families.

20. Section 203.40 is amended by revising the first sentence to read as follows:

§ 203.40 Location of property.

The mortgaged property shall be located within the United States, Puerto Rico, Guam, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, and American Samoa. * * *

21. Section 203.42 is amended by revising paragraph (a) to read as follows:

§ 203.42 Rental properties.

(a) A mortgage on property upon which there is a dwelling to be rented by the mortgagor shall not be eligible for insurance if the property is a part of, or adjacent or contiguous to, a project, or group of similar rental properties, in which the mortgagor has a financial interest in eight or more dwelling units.

* * * * *

22. Section 203.43 is amended by revising paragraph (c)(3) to read as follows:

§ 203.43 Eligibility of miscellaneous type mortgages.

* * * * *

(c) * * *

(3) The mortgage must result in a reduction in regular monthly payments by the mortgagor, except:

(i) When a fixed rate mortgage is given to refinance an adjustable rate mortgage held by a mortgagor who is to occupy the dwelling as a principal residence or secondary residence, as these terms are defined in § 203.18(f); or

(ii) When refinancing a mortgage for a shorter term will result in an increase in the mortgagor's regular monthly payments of no more than $50. In the case of a graduated payment mortgage, the reduction in regular monthly payments means a reduction from the payment due under the existing mortgage for the month in which the refinancing mortgage is executed.

* * * * *

§ 203.43b [Removed and reserved]

23. Section 203.43b is removed and reserved.

§ 203.43f [Amended]

24. Section 203.43f(b) is amended to remove the last sentence.

25. Section 203.43h is amended by revising the introductory text, revising paragraph (b), and revising paragraph (g)(3), to read as follows:

§ 203.43h Eligibility of mortgages on Indian land insured pursuant to section 248 of the National Housing Act.

A mortgage covering a one- to four-family residence located on Indian land shall be eligible for insurance pursuant to section 248 of the National Housing Act (12 U.S.C. 1715z–13), notwithstanding otherwise applicable requirements related to marketability of title, if the mortgage meets the requirements of this subpart as modified by this section and is made by an Indian Tribe or on a leasehold estate, by an Indian who will occupy it as a principal residence. Mortgage insurance on cooperative shares is not authorized under this section.

* * * * *

(b) *Eviction procedures.* Before HUD will insure a mortgage on Indian land, the tribe having jurisdiction over such property must certify to the HUD Field Office that it has adopted and will enforce procedures for eviction of defaulted mortgagors where the insured mortgage has been foreclosed.

* * * * *

(g) * * *

(3) ''Indian tribe'' means any Indian or Alaska native tribe, band, nation, or other organized group or community of Indians or Alaskan natives recognized as eligible for the services provided to Indians or Alaska natives by the Secretary of the Interior because of its status as such an entity, or that is an eligible recipient under chapter 67 of title 31, United States Code. For purposes of engaging in section 248 insured mortgage transactions under this section, an Indian tribe may act through its duly authorized representative.

* * * * *

26. Section 203.43i is amended by revising paragraph (a) to read as follows:

§ 203.43i Eligibility of mortgages on Hawaiian Home Lands insured pursuant to section 247 of the National Housing Act.

(a) *Eligibility.* A mortgage on a homestead lease granted by the Department of Hawaiian Home Lands covering a one- to four-family residence located on Hawaiian home lands is eligible for insurance pursuant to section 247 of the National Housing Act (12 U.S.C. 1715z–12) if the mortgagor is a native Hawaiian who will occupy it as a principal residence, and if the mortgage meets the requirements of this subpart as modified by this section. Mortgage insurance on cooperative shares under § 203.43c on homes in federally impacted areas under § 203.43e is not authorized under this section.

* * * * *

27. Section 203.44 is revised to read as follows:

§ 203.44 Eligibility of advances.

Mortgagees may not make open-end advances under section 225 of the National Housing Act (12 U.S.C. 1715p) in connection with the mortgages insured under this chapter.

28. Section 203.49 is amended by revising the second sentence of the introductory text and by removing the second sentence of paragraph (a) beginning with ''The weekly average * * *'', to read as follows:

§ 203.49 Eligibility of adjustable rate mortgages.

* * * This section shall apply only to mortgage loans described under sections 203(b), 203(h) and 203(k) of the National Housing Act.

* * * * *

29. Section 203.204 is amended by revising paragraph (a) and by revising the third sentence of paragraph (g), to read as follows:

§ 203.204 Requirements and limitations of a plan.

(a) A Plan must assure timely resolution of homeowners' complaints or claims covered under § 203.205. Warranties set forth in a Plan must comply with section 2301(a)(1)–(13) of the Magnuson-Mass Warranty-Federal Trade Commission Improvement Act (15 U.S.C. 2301–2312) along with the requirements and criteria set out in this section.

* * * * *

(g) * * * A Plan must contain pre-arbitration conciliation provisions at no cost to the homeowner, and provision for judicial resolution of disputes, but arbitration, which must be available to a homeowner during the entire term of the coverage contract, must be an assured recourse for a dissatisfied homeowner.

* * * * *

30. Section 203.251 is amended by revising paragraph (s) to read as follows:

§ 203.251 Definitions.

* * * * *

(s) *State* includes the several States, Puerto Rico, the District of Columbia, Guam, the Commonwealth of the Northern Mariana Islands, American Samoa, and the Virgin Islands.

* * * * *

31. Section 203.255 is amended by revising paragraph (b)(2) to read as follows:

§ 203.255 Insurance of mortgage.

(b) * * *

(2) An application for insurance of the mortgage in a form prescribed by the Secretary;

* * * * *

§ 203.265 [Amended]

32. Section 203.265(b) is amended in the last sentence to remove the phrase ''Treasury Fiscal Requirements Manual'' and add in its place the phrase ''Treasury Financial Manual.''

33. Section 203.281 is amended by revising paragraph (b)(1) to read as follows:

§ 203.281 Calculation of one-time MIP.

* * * * *

(b)(1) The Commissioner shall determine the applicable premium percentage in accordance with sound financial and actuarial practice.

* * * * *

§ 203.284 [Amended]

34. Section 203.284 is amended by:

a. Removing the second sentence in paragraph (a)(1);

b. Removing the phrase ''pursuant to paragraph (b)(1)(i) or (b)(2)(i) of this section,'' in paragraph (c); and

c. Removing the phrase ''Treasury Fiscal Requirements Manual'' in the last sentence of paragaph (e), and adding in its place the phrase ''Treasury Financial Manual.''

35. Section 203.285 is amended by revising the second sentence of paragraph (c) to read as follows:

§ 203.285 Fifteen-year mortgages: Calculation of up-front and annual MIP on or after December 26, 1992.

* * * * *

(c) *Applicability of certain provisions.* * * * The provisions of paragraphs (c), (d), (e), and (g) of § 203.284 also shall be applicable to mortgages subject to premiums under this section.

* * * * *

36. Section 203.346 is amended by revising the first sentence to read as follows:

§ 203.346 Postponement of foreclosure—mortgagors in military service.

If at any time during default the mortgagor is a ''Person in military service,'' as such term is defined in the Soldiers' and Sailors' Civil Relief Act of 1940, the period during which the mortgagor is in such service shall be excluded in computing the period within which the mortgagee shall commence foreclosure or acquire the property by other means as provided in § 203.355 of this subpart. * * *

37. Section 203.356 is revised to read as follows:

§ 203.356 Notice of foreclosure and pre-foreclosure sale; reasonable diligence requirements.

(a) *Notice of foreclosure and pre-foreclosure sale.* The mortgagee must give notice to the Secretary, in a format prescribed by the Secretary, within 30 days after the institution of foreclosure proceedings. The mortgagee must give notice to the Secretary, in a format prescribed by the Secretary, within the time-frame prescribed by the Secretary, of the acceptance of any mortgagor into the pre-foreclosure sale procedure.

(b) *Reasonable diligence.* The mortgagee must exercise reasonable diligence in prosecuting the foreclosure proceedings to completion and in acquiring title to and possession of the property. A time frame that is determined by the Secretary to constitute ''reasonable diligence'' for each State is made available to mortgagees.

38. Section 203.378 is amended by revising paragraph (c)(1) to read as follows:

§ 203.378 Property condition.

* * * * *

(c) * * *

(1) Damage by fire, flood, earthquake, hurricane, or tornado;

* * * * *

39. Section 203.379 is amended by revising paragraph (a), introductory text, and paragraph (b), introductory text, to read as follows:

§ 203.379 Adjustment for damage or neglect.

(a) If the property has been damaged by fire, flood, earthquake, hurricane, or tornado, or, for mortgages insured on or after January 1, 1977, the property has suffered damage because of the mortgagee's failure to take action as required by § 203.377, the damage must be repaired before conveyance of the property or assignment of the mortgage to the Secretary, except under the following conditions:

* * * * *

(b) For mortgages insured under firm commitments issued on or after November 19, 1992, or under direct endorsement processing where the credit worksheet was signed by the mortgagee's underwriter on or after November 19, 1992, the provisions of paragraph (a) of this section apply and, in addition, if the property has been damaged during the time of the mortgagee's possession by events other than fire, flood, earthquake, hurricane, or tornado, or if it was damaged notwithstanding reasonable action by the mortgagee as required by § 203.377 of this part, the mortgagee must provide notice of such damage to the Secretary and may not convey until directed to do so by the Secretary. The Secretary will either:

* * * * *

40. Section 203.380 is amended by revising paragraph (a)(1)(i) to read as follows:

§ 203.380 Certificate of property condition.

(a) * * *

(1) * * *

(i) Undamaged by fire, flood, earthquake, hurricane or tornado; and

* * * * *

41. Section 203.390 is amended by revising paragraph (b)(1) to read as follows:

§ 203.390 Waiver of title—mortgages or property formerly held by the Secretary.

* * * * *

(b) * * *

(1) If a property held by the Secretary is sold by the Secretary who also insures a mortgage financing the sale, and the mortgage is later reassigned to the Secretary or the property covered by the mortgage is later conveyed to the Secretary, the Secretary will not object to title by reason of any lien or other adverse interest that was senior to the mortgage on the date the mortgage was filed for record, except where the lien or other adverse interest arose from a lien or interest that had already been recorded against the mortgagor.

* * * * *

42. Section 203.402 is amended by revising paragraphs (b), (c) and (k)(1) to read as follows:

§ 203.402 Items included in payment—conveyed and non-conveyed properties.

* * * * *

(b) Special assessments, which are noted on the application for insurance or which become liens after the insurance of the mortgage.

(c) Hazard insurance premiums on the mortgaged property not in excess of a *reasonable rate* as defined in § 203.379(a)(4).

* * * * *

(k)(1) For properties conveyed to the Secretary, an amount equivalent to the debenture interest which would have been earned, as of the date such payment is made, on the portion of the insurance benefits paid in cash, if such portion had been paid in debentures, except that:

(i) When the mortgagee fails to meet any one of the applicable requirements of §§ 203.355, 203.356(b), 203.359, 203.360, 203.365, 203.606(b)(1), or 203.366 within the specified time and in a manner satisfactory to the Secretary (or within such further time as the Secretary may approve in writing), the interest allowance in such cash payment shall be computed only to the date on which the particular required action should have been taken or to which it was extended;

(ii) When the mortgagee fails to meet the requirements of § 203.356(a) of this part within the specified time and in a manner satisfactory to the Secretary (or within such further time as the Secretary may approve in writing), the interest allowance in such cash payment shall be computed to a date set administratively by the Secretary.

* * * * *

43. An undesignated center heading ''GRADUATED PAYMENT MORTGAGES'' is added after § 203.435 and before § 203.436.

44. Section 203.502 is amended to revise the first sentence of paragraph (a) and all of paragraph (b) to read as follows:

§ 203.502 Responsibility for servicing.

(a) After January 10, 1994, servicing of insured mortgages must be performed by a mortgagee that is approved by HUD to service insured mortgages. * * *

* * * * *

(b) Whenever servicing of any mortgage is transferred from one mortgagee or servicer to another, notice of the transfer of service shall be delivered:

(1) By the transferor mortgagee or servicer to the mortgagor. The notification shall be delivered not less than 15 days before the effective date of the transfer and shall contain the information required in § 3500.21(e)(2) of this title; and

(2) By the transferee mortgagee or servicer:

(i) To the mortgagor. The notification shall be delivered not less than 15 days before the effective date of the transfer and shall contain the information required in § 3500.21(e)(2) of this title; and

(ii) To the Secretary. This notification shall be delivered within 15 days of the transfer, in a format prescribed by the Secretary.

* * * * *

45. Section 203.604 is amended by revising the second sentence of paragraph (b) to read as follows:

§ 203.604 Contact with the mortgagor.

* * * * *

(b) * * * If default occurs in a repayment plan arranged other than during a personal interview, the mortgagee must have a face-to-face meeting with the mortgagor, or make a reasonable attempt to arrange such a meeting within 30 days after such default and at least 30 days before foreclosure is commenced, or at least 30 days before assignment is requested if the mortgage is insured on Hawaiian home land pursuant to section 247 or Indian land pursuant to section 248 or if assignment is requested under § 203.350(d) for mortgages authorized by section 203(q) of the National Housing Act.

* * * * *

46. Section 203.670 is amended by revising paragraph (a) to read as follows:

§ 203.670 Conveyance of occupied property.

(a) It is HUD's policy to reduce the inventory of acquired properties in a manner that expands homeownership opportunities, strengthens neighborhoods and communities, and ensures a maximum return to the mortgage insurance fund.

* * * * *

47. Section 203.679 is amended by revising paragraph (b)(4) to read as follows:

§ 203.679 Continued occupancy after conveyance.

* * * * *

(b) * * *

(4) Assignment of the property by the Secretary to a different use or program.

§ 203.685 [Removed]

48. Section 203.685 is removed.

PART 206—HOME EQUITY CONVERSION MORTGAGE INSURANCE

49. The authority citation for 24 CFR part 206 continues to read as follows:

Authority: 12 U.S.C. 1715b, 1715z–1720; 42 U.S.C. 3535(d).

§ 206.3 [Amended]

50. Section 206.3 is amended by removing the last sentence of the definition of ''*Maximum claim amount*''.

51. Section 206.9 is amended by revising the paragraph heading of paragraph (b) to read as follows:

§ 206.9 Eligible mortgagees.

* * * * *

(b) *HUD approved mortgagees.*

§ 206.13 [Removed and reserved]

52. Section 206.13 is removed and reserved.

53. Section 206.17 is amended by revising paragraph (a) to read as follows:

§ 206.17 General.

(a) *Payment options.* A mortgage shall initially provide for the tenure payment option (§ 206.19(a)), the term payment option (§ 206.19(b)), or the line of credit payment option (§ 206.19(c)), or a combination as provided in § 206.25(d), subject to later change in accordance with § 206.26.

* * * * *

§ 206.45 [Amended]

54. Section 206.45(b) is amended to remove the second sentence.

§ 206.121 [Amended]

55. Section 206.121(c) is amended to remove the citation ''§ 206.27(e)'' and to add in its place the citation ''§ 206.27(d).''

PART 221—LOW COST AND MODERATE INCOME MORTGAGE INSURANCE

56. The authority citation for part 221 continues to read as follows:

Authority: 12 U.S.C. 1707(a), 1715b, and 1715*l*; 42 U.S.C. 3535(d).

57. Section 221.45 is revised to read as follows:

§ 221.45 Mortgage obligation in multiples.

The mortgage shall involve a principal obligation in multiples of $1.

PART 233—EXPERIMENTAL HOUSING MORTGAGE INSURANCE

58. The authority citation for part 233 is revised to read as follows:

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

59. Section 233.5 is amended by revising paragraph (a) introductory text and paragraph (b) to read as follows:

§ 233.5 Cross-reference.

(a) To be eligible for insurance under this subpart, a mortgage or home improvement loan shall meet the eligibility requirements for insurance under § 203.1 *et seq.* (part 203, subpart A); § 213.501 *et seq.* (part 213, subpart C); § 220.1 *et seq.* (part 220, subpart A); § 221.1 *et seq.* (part 221, subpart A); § 226.1 *et seq.* (part 226, subpart A); § 234.1 *et seq.* (part 234, subpart A); § 235.1 *et seq.* (part 235, subpart A); or § 237.1 *et seq.* (part 237, subpart A) of this chapter, except that:

* * * * *

(b) For the purposes of this subpart, all references in parts 203, 213, 220, 221, 226, 234, 235, and 237 of this chapter to sections 203, 213, 220, 221, 809, 234, 235, and 237 of the National Housing Act shall be construed to refer to section 233 of the Act.

PART 234—CONDOMINIUM OWNERSHIP MORTGAGE INSURANCE

60. The authority for part 234 continues to read as follows:

Authority: 12 U.S.C. 1715qb and 1715y; 42 U.S.C. 3535(d). Section 234.520(a)(2)(ii) is also issued under 12 U.S.C. 1707(a).

61. Section 234.1 is amended by revising paragraph (n) to read as follows:

§ 234.1 Definitions used in this subpart.

* * * * *

(n) *State* includes the several States, Puerto Rico, the District of Columbia, Guam, the Commonwealth of the Northern Mariana Islands, American Samoa, and the Virgin Islands.

* * * * *

62. Section 234.11 is added to read as follows:

§ 234.11 Disclosure regarding interest due upon mortgage prepayment.

Each mortgagee with respect to a mortgage under this part shall, at or before closing with respect to any such mortgage, provide the mortgagor with written notice in a form prescribed by the Commissioner describing any requirements the mortgagor must fulfill upon prepayment of the principal amount of the mortgage to prevent the accrual of any interest on the principal amount after the date of such prepayment.

63. Section 234.16 is amended by adding a new paragraph (d) to read as follows:

§ 234.16 Certificate of nondiscrimination by mortgagor.

* * * * *

(d) That buildings having four (4) or more units, which were built for first occupancy after March 13, 1991, were constructed in compliance with the Fair Housing Act new construction requirements in 24 CFR 100.205.

64. Section 234.25 is amended by revising paragraph (b) to read as follows:

§ 234.25 Mortgage provisions.

* * * * *

(b) *Mortgage multiples.* The mortgage shall involve a principal obligation in a multiple of $1.

* * * * *

65. Section 234.52 is amended by revising paragraph (c) to read as follows:

§ 234.52 Refinancing of existing mortgages.

* * * * *

(c) The mortgage must result in a reduction in regular monthly payments by the mortgagor, except:

(1) When a fixed rate mortgage is given to refinance an adjustable rate mortgage held by a mortgagor who is to occupy the dwelling as a principal residence or secondary residence, as these terms are defined in § 237.27(e); or

(2) When refinancing a mortgage for a shorter term will result in an increase in the mortgagor's regular monthly payments of no more than $50. In the case of a graduated payment mortgage, the reduction in regular monthly payments means a reduction from the payment due under the existing mortgage for the month in which the refinancing mortgage is executed;

* * * * *

66. Section 234.54 is added, under the undesignated center heading ''ELIGIBLE MORTGAGES,'' to read as follows:

§ 234.54 Eligibility of assigned mortgages and mortgages covering acquired property.

The Commissioner may insure under this part, without regard to any limitation upon eligibility contained in this subpart, any mortgage assigned to the Commissioner in connection with payment under a contract of mortgage insurance, or executed in connection with a sale by the Commissioner of any property acquired in the settlement of an insurance claim under any section or title of the National Housing Act.

§ 234.67 [Removed and reserved]

67. Section 234.67 is removed and reserved.

68. The undesignated center heading ''OPEN-END ADVANCES'' immediately preceding § 234.70 is removed.

69. Section 234.70 is revised to read as follows:

§ 234.70 Eligibility of open-end advances.

Mortgagees may not make open-end advances under section 255 of the National Housing Act in connection with mortgages insured under this chapter.

PART 280—NEHEMIAH HOUSING OPPORTUNITY GRANTS PROGRAM

70. The authority citation for 24 CFR part 280 continues to read as follows:

Authority: 12 U.S.C. 1715l note; 42 U.S.C. 3535(d).

71. Section 280.330 is amended by revising the section heading and paragraph (c)(2) to read as follows:

§ 280.330 Loan and Profit.

* * * * *

(c) * * *

(2) Loan and Profit—Any amounts remaining after distribution of the down payment shall be shared equally between the Secretary and the family, but only to the extent that the Secretary recovers an amount equal to the amount of the loan originally made to the family under this section. If such remaining amounts are insufficient for the Secretary to recover the full amount of the loan made under this section, the remaining balance of the second mortgage shall be cancelled and shall not be transferred to a subsequent purchaser.

* * * * *

PART 291—DISPOSITION OF HUD-ACQUIRED SINGLE FAMILY PROPERTY

72. The authority for 24 CFR part 291 continues to read as follows:

Authority: 12 U.S.C. 1790 and 1715(b); 42 U.S.C. 1441, 1441a, 1551a, and 3535(d).

73. Section 291.100 is amended by revising the first sentence of paragraph (a)(3) and the introductory text in paragraph (a)(4) to read as follows:

§ 291.100 General policy.

(a) * * *

(3) Except as provided in paragraph (a)(4) of this section, tenants in occupancy will not be offered the right of first refusal to purchase the property. * * *

(4) HUD tenants in occupancy will be offered the right of first refusal to purchase property where:

* * * * *

74. Section 291.105 is amended by revising the first sentence of paragraph (e) and the first sentence of paragraph (h)(2), to read as follows:

§ 291.105 Competitive sales procedure.

* * * * *

(e) *Full price offers.* HUD field offices that operate under a ''full price offer'' program open offers at specified times during the 10-day bidding period. * * *

* * * * *

(h) * * *

(2) All bids must be accompanied by earnest money deposits in the form of a cash equivalent as prescribed by the Secretary, or a certification from the real estate broker that the earnest money has been deposited in the broker's escrow account. * * *

* * * * *

75. Section 291.110 is amended by revising the first sentence of paragraph (b)(1) to read as follows:

§ 291.110 Other sales procedures.

* * * * *

(b) *Direct sales to displaced persons.* (1) At the discretion of the Field Office, properties eligible for insured financing are offered for direct sale, at a discount of 10 percent off the list price, to displaced persons who will occupy the properties. * * *

* * * * *

76. Section 291.115 is amended by revising paragraph (b)(2) to read as follows:

§ 291.115 Insured sales.

* * * * *

(b) * * *

(2) For an owner-occupant purchaser, the mortgage amount is based on the bid price plus any allowable pre-paids (e.g., taxes) and financing or closing costs, up to local maximum mortgage amounts. For investor purchasers without rehabilitation loans insured under § 203.50 of this chapter, the mortgage amount is limited to 75 percent of the bid price for one-unit properties, and 85 percent for two- to four-unit properties, up to local maximum mortgage amounts. Pre-paids, financing or closing costs may not be included in the mortgage amount for such investor purchasers. For investor purchasers with rehabilitation loans insured under § 203.50 of this chapter, the mortgage amount is calculated as provided in § 203.50(f) of this chapter and the bid price is used as the Commissioner's estimate of the value of the property before rehabilitation.

Dated: June 13, 1996.

Nicolas P. Retsinas,

Assistant Secretary for Housing-Federal Housing Commissioner.

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Federal Register

Tuesday
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Part VIII

Department of Education

Final Funding Priority for Fiscal Years 1996–1997 for a Rehabilitation Research and Training Center; Inviting Applications for a New Award Under the Rehabilitation Research and Training Center Program for Fiscal Year 1997; Notices

DEPARTMENT OF EDUCATION

National Institute on Disability and Rehabilitation Research; Notice of a Final Funding Priority for Fiscal Years 1996–1997 for a Rehabilitation Research and Training Center

AGENCY: Department of Education.

SUMMARY: The Secretary announces a final funding priority for the Rehabilitation Research and Training Center (RRTC) Program under the National Institute on Disability and Rehabilitation Research (NIDRR) for fiscal years 1996–1997. The Secretary takes this action to focus research attention on areas of national need. This priority is intended to improve rehabilitation services and outcomes for individuals with disabilities.

EFFECTIVE DATE: This priority takes effect on August 8, 1996.

FOR FURTHER INFORMATION CONTACT: Betty Jo Berland, U.S. Department of Education, 600 Independence Avenue, S.W., Switzer Building, Room 3424, Washington, D.C. 20202–2601. Telephone: (202) 205–9739. Individuals who use a telecommunications device for the deaf (TDD) may call the TDD number at (202) 205–8133. Internet: Betty-Jo-Berland@ed.gov.

SUPPLEMENTARY INFORMATION: This notice contains a final funding priority to establish an RRTC for research related to managed health care for individuals with disabilities.

NIDRR is in the process of developing a revised long-range plan. The final funding priority in this notice is consistent with the long-range planning process. This final funding priority supports the National Education Goal that calls for all Americans to possess the knowledge and skills necessary to compete in a global economy and exercise the rights and responsibilities of citizenship.

Note: This notice of final funding priority does not solicit applications. A notice inviting applications under this competition is published in a separate notice in this issue of the Federal Register.

On April 22, 1996, the Secretary published a notice of proposed priority in the Federal Register (61 FR 17818–17821). The Department of Education received nineteen letters commenting on the notice of proposed priority by the deadline date. Three additional comments were received after the deadline date and were not considered in this response. Technical and other minor changes—and suggested changes the Secretary is not legally authorized to make under statutory authority—are not addressed. All of the comments supported the need for the proposed RRTC, and some made suggestions for modifications to the Rehabilitation Research and Training Center (RRTC) in managed care.

Analysis of Comments and Changes

The following paragraphs first discuss those comments that pertain to the priority as a whole, and then discuss those that address the specific activities, or ''bullets'', within the priority.

General Comments

Comment: One commenter suggested that the center grant be awarded to an institution that specializes in serving the health care needs of children, and another suggested that the health care of children with disabilities should be a central focus of the RRTC.

Discussion: The Secretary cannot limit the field of eligible applicants beyond that authorized by the statute and program regulations, which permit any organization operating in affiliation with an institution of higher education or a provider of rehabilitation or other appropriate services to apply for the Center grant. Furthermore, because the Bureau of Maternal and Child Health in the Department of Health and Human Services (HHS) has developed an extensive agenda for research on managed health care for children with disabilities, the Center to be funded under this priority is directed toward health care needs of adults.

Changes: None.

Comment: A number of commenters urged that the priority require the Center to include a focus on certain subpopulations of individuals with disabilities, such as children or adolescents, the elderly, residents of rural areas, or persons with specific types of disabling conditions.

Discussion: The Secretary believes that this should be a cross-disability study, with a unique emphasis on working age adults. Applicants are not precluded from addressing the health care needs of any groups of individuals with disabilities, but due to the scope and complexity of the issue of managed care, and the need to respond to unanticipated developments in health care delivery, the Secretary elects not to require all applicants to structure research programs that focus on particular subgroups.

Changes: None.

Comment: Several commenters suggested the addition or further specification of various requirements to the work scope of the Center, including: studies of specific health care services; educational programs for specific categories of professional service providers; focus on rural health care delivery; models for services to individuals with comorbidities; transition from pediatric to adult care; and examination of comparable benefits between health care and vocational rehabilitation funding streams.

Discussion: The Secretary believes that many of the suggested additional requirements are important studies, but points out that this RRTC will not have unlimited resources, and that researchers should have flexibility to choose the optimum approach to addressing the general challenges of the priority, as well as addressing the other specific requirements of the priority. The Secretary believes that many of these specific suggestions could be addressed by an applicant in responding to this priority, but the Secretary declines to require them of all applicants.

There is a growing body of research on issues of managed health care for persons with disabilities being conducted by various Federal agencies, and there are other ongoing or planned studies that may provide appropriate venues for addressing many of these additional questions. The Secretary reminds potential applicants that some of these problems may be addressed, with appropriate coordination with the RRTC, in discrete studies under NIDRR's Field-Initiated Research program.

Changes: None.

Comment: One commenter suggested that the proposed RRTC should be a resource for disseminating new health policy analysis methods from other medical specialties into the rehabilitation medicine specialty.

Discussion: The Secretary does endorse the use of the best and most appropriate methods of health care analysis in the field of medical rehabilitation. However, the Secretary points out that the primary purpose of this Center is not the improvement of medical rehabilitation, but rather the improvement of the managed care delivery system, with a focus on primary care, acute care, and long-term care, as well as on rehabilitative care. NIDRR currently funds an RRTC on medical rehabilitation research and expects to announce a competitive priority to continue research in this area in fiscal year 1997. Therefore, the Secretary believes that this activity would not be an appropriate use of resources in this Center.

Changes: None.

Comment: One commenter suggested that NIDRR use the term ''significant disability'' and the definition of that term contained in the Americans with

Disabilities Act to define the target population of this Center.

Discussion: NIDRR is authorized and funded under the Rehabilitation Act of 1973, as amended and therefore must relate its activities to persons who have disabilities as defined by the Rehabilitation Act.

Changes: None.

Comment: Two commenters expressed the opinion that the Background statement did not make it clear that physiatrists provided primary care by default, and not because of a professional mission or obligation to do so.

Discussion: The Secretary intended that the priority convey the relationship between the lack of informed primary care for individuals with disabilities and the demand for rehabilitation medicine professionals to fill this void. Provision of primary care by rehabilitation medicine providers, including physiatrists, has been, at least to date, by default rather than by design. However, because the information was contained in the Background statement as descriptive information, and would not affect directly the activities to be performed under the grant, no changes are made.

Changes: None.

Comment: One commenter suggested that the priority should focus on older as well as working age adults with disabilities, because of the similarity of health care concerns in areas such as prevention of secondary conditions and quality of life.

Discussion: The Secretary agrees that managed care for older individuals with disabilities is an important area. However, as the priority states, there is considerable research supported by HHS on managed care in elderly populations, most of whom are enrolled in Medicare. Working age individuals with disabilities have some unique concerns with the health care delivery system, for example, the availability of coverage and the scope of services covered by commercial insurance. These individuals are more likely to need family coverage or support for technologies and services related to employment. Thus, the Secretary believes that the needs of working age disabled persons should be the primary focus of this Center. The health care needs of working age disabled persons under managed care is an area that is not adequately addressed at present. In addition, this is an area in which NIDRR has unique responsibilities and the ability to make a significant contribution to the overall managed health care policy debate.

Changes: None.

Comment: Several commenters discussed the significance of the ways in which ''auxiliary'' services such as technology, personal assistance services (PAS) or long-term care, transportation, and housing are handled in a health services plan, and urged focus on this issue.

Discussion: The proposed priority does reference the continuum of care, PAS, and access to technology as components of a health care system for individuals with disabilities. The Secretary believes that the priority is explicit in requiring attention to a comprehensive continuum of care.

Changes: None.

Comments: One commenter, representing the Administration on Aging (AoA), stated that the AoA sponsored only a limited amount of research on managed care, rather than the ''significant program'' referred to in the Background statement.

Discussion: The Secretary agrees to describe the research program of the AoA in the terms suggested by that agency.

Changes: The AoA has been dropped from the listing of agencies that are establishing significant programs of research into managed care, and a separate sentence has been added stating that ''managed care research also is being conducted by the Administration on Aging.

Comments on the First Required Activity

Comment: Two commenters expressed the opinion that the first prescribed activity of developing a method to identify individuals whose health care needs require special approaches under managed care would be difficult to accomplish. At the same time, several commenters suggested that the priority could be strengthened by adding an evaluation of the experiences of individuals with diverse types of disabilities under various models of managed care and fee-for-service care. Another commenter suggested that coordination with the National Committee on Vital and Health Statistics (NCVHS), which is leading an effort to develop voluntary standardized sets of disability descriptors for health encounters, would be useful to the Center in its efforts to develop methods to identify individuals with disabilities who need special health care approaches.

Discussion: The Secretary believes that a prerequisite to designing a comprehensive health care system is an understanding of what populations of disabled individuals are likely to need special arrangements under managed health care, and to have some parameters for describing and identifying that population. The Secretary agrees with the commenters that a definitive understanding of the pertinent experiences of individuals with disabilities under various types of managed care as well as under traditional approaches would be useful to the Center in determining the characteristics of persons likely to need special managed care arrangements.

Changes: The first bullet has been revised to encompass an assessment of managed care and fee-for-service care experiences of individuals with disabilities, and to include coordination with the NCVHS and other large-scale efforts to routinize the collection of disability-related information in health care records.

Comments on the Second Required Activity

Comment: One commenter stated that the requirement in the second bullet to use existing data may be unrealistic, due to the absence or unavailability of the types of data that might be needed. The commenter suggested a revision to require the use of existing data only ''where possible.'' One commenter suggested that the priority should require the center, working with other researchers and government agencies, to develop both qualitative and quantitative research examining the impact of managed care arrangements on quality of care, cost of care, and access to specialty providers, and to identify gaps in training as well as gaps in research, as currently required.

Discussion: The Secretary suggested the use of existing data as a means of achieving economy and efficiency. The Secretary agrees that applicants should not be restricted in their approach to answering important research questions, as long as they demonstrate that they are using the most efficient means. The Secretary believes that the parameters of quality, cost, and access to specialists are critical elements in assessing the impact of managed care on individuals with disabilities, and that coordinated activity is desirable in studying these factors.

Changes: The second bullet has been revised to include the words ''where possible'', and to stress coordinated qualitative and quantitative research on the impact of managed care.

Comments related to the third required activity

Comment: Several commenters suggested a stronger emphasis on the involvement of consumers, particularly in the development of quality indicators

for managed health care programs and providers. Two commenters also pointed out that there are current efforts of the National Committee for Quality Assurance (NCQA), the Robert Wood Johnson Foundation (RWJ), and the Assistant Secretary for Planning and Evaluation (ASPE) in the Department of Health and Human Services (ASPE) in this area, and urged that the Center be required to coordinate with those efforts.

Discussion: The Secretary agrees that individuals with disabilities and their families, where appropriate, must be involved in all phases of the Center's activities and further agrees to emphasize the need for this involvement in the development of quality indicators, and also that coordination with other national efforts is essential.

Changes: The third priority requirement has been revised to include an emphasis on consumer involvement and also coordination with other national efforts in the development of standards.

Comments on the fourth required activity

Comment: One commenter suggested that this activity should emphasize the involvement of consumer and organizations representing consumers in the development of these educational programs, while another commenter stated that the priority should state explicitly that the educational programs should also be implemented. A third commenter suggested that the training programs should be based on an evaluation of the factors likely to influence health plan decision-making by individuals with disabilities. One commenter suggested that the Center should work with NIDRR and other Federal planning and demonstration offices in designing consumer education programs.

Discussion: The Secretary agrees that consumers must be involved in the development of the educational programs, as in all phases of the Center's activities, and also that they should be involved in the implementation. The Secretary also agrees that the educational program should be knowledge-based, but declines to specify what type of research should be conducted to ascertain the necessary knowledge. The Secretary emphasizes that the Center will be required to work with NIDRR and with a range of Federal planning agencies and their grantees on all phases of the Center's activities, and does not want to suggest that it is more important on this particular bullet.

Changes: The fourth bullet is revised to note the need to involve consumers and their organizations in the development of the training, and the need to implement the training with their involvement. The bullet also requires that the educational programs be based on a knowledge of consumer training needs.

Comments on the sixth required activity

Comment: One commenter suggested that the Center be required to attend the two-day National Conference on Managed Care and People with Disabilities that will be sponsored by the Department of Health and Human Services, and integrate the conference's research and training recommendations into its goals and directions. One commenter suggested that the Department of Veterans Affairs be added to the list of coordinating agencies, while others recommended coordination with the Robert Wood Johnson (RWJ) foundation and with offices of HHS is addition to those named in the priority. A commenter suggested that the Center be required to coordinate with NIDRR's Model Systems in Spinal Cord Injury, Traumatic Brain Injury, and Burns to make use of information available from those systems. One commenter suggested that parents and family care givers should be represented on the Advisory Board.

Discussion: The Secretary agrees that all of these are excellent suggestions. The Secretary has the flexibility to address the issue of attendance at the National Conference in the negotiation of the grant award. However, the Secretary does not want to prescribe the ways in which the Center must meet the requirements to represent consumers on the advisory board, and prefers to permit each applicant to propose how it will meet that requirement. With respect to other Federal agencies, the Secretary believes that the Department of Veterans Affairs will be a source of information, as will many units of HHS in addition to those named in the priority. Among private sector sponsors of health care research, the RWJ Foundation merits special inclusion because of its extensive body of research on managed care and disability and on consumer directed activities of personal assistance services and independent living. However, the Secretary believes that the priority as written, along with this discussion, provides sufficient guidance to applicants on the need to develop a substantial advisory committee with a wide scope of interests. The Secretary believes that each applicant should have the freedom within that framework to propose and defend an Advisory Committee on its own choosing.

Changes: None.

Rehabilitation Research and Training Centers (RRTCs)

Authority for the RRTC program of NIDRR is contained in section 204(b)(2) of the Rehabilitation Act of 1973, as amended (29 U.S.C. 760–762). Under this program the Secretary makes awards to public and private organizations, including institutions of higher education and Indian tribes or tribal organizations for coordinated research and training activities. These entities must be of sufficient size, scope, and quality to effectively carry out the activities of the Center in an efficient manner consistent with appropriate State and Federal laws. They must demonstrate the ability to carry out the training activities either directly or through another entity that can provide such training.

The Secretary may make awards for up to 60 months through grants or cooperative agreements. The purpose of the awards is for planning and conducting research, training, demonstrations, and related activities leading to the development of methods, procedures, and devices that will benefit individuals with disabilities, especially those with the most severe disabilities.

Under the regulations for this program (see 34 CFR 352.32) the Secretary may establish research priorities by reserving funds to support particular research activities.

Description of the Rehabilitation Research and Training Center Program

RRTCs are operated in collaboration with institutions of higher education or providers of rehabilitation services or other appropriate services. RRTCs serve as centers of national excellence and national or regional resources for providers and individuals with disabilities and the parents, family members, guardians, advocates or authorized representatives of the individuals.

RRTCs conduct coordinated and advanced programs of research in rehabilitation targeted toward the production of new knowledge to improve rehabilitation methodology and service delivery systems, alleviate or stabilize disabling conditions, and promote maximum social and economic independence of individuals with disabilities.

RRTCs provide training, including graduate, pre-service, and in-service training, to assist individuals to more effectively provide rehabilitation

services. They also provide training including graduate, pre-service, and in-service training, for rehabilitation research personnel and other rehabilitation personnel.

RRTCs serves as informational and technical assistance resources to providers, individuals with disabilities, and the parents, family members, guardians, advocates, or authorized representatives of these individuals through conferences, workshops, public education programs, in-service training programs and similar activities.

NIDRR encourages all Centers to involve individuals with disabilities and minorities as recipients in research training, as well as clinical training.

Applicants have considerable latitude in proposing the specific research and related projects they will undertake to achieve the designated outcomes; however, the regulatory selection criteria for the program (34 CFR 352.31) state that the Secretary reviews the extent to which applicants justify their choice of research projects in terms of the relevance to the priority and to the needs of individuals with disabilities. The Secretary also reviews the extent to which applicants present a scientific methodology that includes reasonable hypothese, methods of data collection and analysis, and a means to evaluate the extent to which project objectives have been achieved.

The Department is particularly interested in ensuring that the expenditure of public funds is justified by the execution of intended activities and the advancement of knowledge and, thus, has built this accountability into the selection criteria. Not later than three years after the establishment of any RRTC, NIDRR will conduct one or more reviews of the activities and achievements of the Center. In accordance with the provisions of 34 CFR 75.253(a), continued funding depends at all times on satisfactory performance and accomplishment.

General

The following requirements apply to this RRTC pursuant to the priority unless noted otherwise:

Each RRTC must conduct an integrated program of research to develop solutions to problems confronted by individuals with disabilities.

Each RRTC must conduct a coordinated and advanced program of training in rehabilitation research, including training in research methodology and applied research experience, that will contribute to the number of qualified researchers working in the area of rehabilitation research.

Each Center must disseminate and encourage the use of new rehabilitation knowledge. They must publish all materials for dissemination or training in alternate formats to make them accessible to individuals with a range of disabling conditions.

Each RRTC must involve individuals with disabilities and, if appropriate, their family members, as well as rehabilitation service providers in planning and implementing the research and training programs, in interpreting and disseminating the research findings, and in evaluating the Center.

Priorities

Under 34 CFR 75.105(c)(3), the Secretary gives an absolute preference to applications that meet the following priority. The Secretary will fund under this competition only applications that meet this absolute priority:

Priority: Health Care for Individuals with Disabilities—Issues in Managed Health Care

Background

Individuals with disabilities have a vital interest in high quality health care, and important interests in the reshaping of the health care delivery system. To begin, they are higher than average users of health services (NMES, 1987), and are more likely to be dependent on quality health care services to prevent secondary disabilities and maintain quality of life. Individuals with disabilities are more likely to be insured under public programs—Medicare and Medicaid—and thus are particularly concerned with the directions of public policy in these programs (LaPlante, 1996). Individuals with disabilities are more likely to be dependent on their health care programs for a wide range of services intended to assure their quality of life and independence, particularly as health care insurers usually control access to funding for personal assistance services and assistive technology.

The central health care issue for individuals with disabilities is access to appropriate, high quality health care. Appropriate care must be timely, of high quality, in sufficient quantity, and accessible both physically and programmatically. For individuals with disabilities, appropriate care also generally implies an integrated continuum of care as necessary, and consumer involvement in the care decisions and implementation. A comprehensive continuum of care, including primary care, acute care, rehabilitation, and long-term care, is key to any health care delivery system for individuals with disabilities.

The health care needs of individuals with disabilities differ from those of the general population in many important aspects (DeJong, 1995). They are at greater risk of acquiring certain medical conditions, often experience these conditions differently, and may require a more extensive therapeutic intervention. Individuals with disabilities often are vulnerable to secondary conditions that may exacerbate the original disability. For this reason, as well as for costs related to the original impairment, persons with disabilities are likely to need more health care and thus to be particularly affected by cost constraints that may affect the volume or quality of services available.

In recent years there has been a significant change in the way health care is delivered and reimbursed. Historically, most of the insured population (including individuals with disabilities) received their health care through fee-for-service health care plans. However, various forms of managed care increasingly are the typical mode of organizing and delivering health care in the private sector, and segments of the Medicaid and Medicare populations have been enrolled in managed care plans. There are many varieties of managed care, ranging from the model of a case manager in a fee-for-service system, through preferred provider arrangements, to the HMO. Regardless of how managed care is operationalized, the essential features are that it is a cost-driven model paid for by a capitation method with strict controls on the volume and costliness of services to be provided to an individual with a given diagnosis. While traditional fee-for-service systems were said to reward the provider in direct proportion to the amount of services rendered, i.e., more services given equals more fees collected, managed care operates with an opposite set of incentives, often rewarding the provider for such things as low average costs, or fewer than average patient visits per diagnostic category. The provider in turn manages the care of the patient through gatekeeping practices that individuals with disabilities fear may limit access to specialists or higher-cost services. One challenge in improving health care for all individuals is to change the incentive-reward systems for gatekeepers, and all providers, from those based on cost savings to those based on quality of outcomes achieved.

A managed care system, particularly one without the funding constraints typically imposed by capitated managed care, has ideal elements of a system of

care for individuals with disabilities. These elements include case management, with an opportunity for the primary care provider or case manager to become familiar with the needs of the individual consumer; coordination of interventions of a variety of specialists; often a single location that increases the physical accessibility of a variety of services and specialists; preventive health care; health education; coordination of medications; a frequent preference for alternative or holistic therapies (such as stress reduction, nutritional education, or exercise) over more invasive procedures that many consumers resent; and a central focus for quality assurance and consumer input.

The American Hospital Association has stated that, managed care is based on the premise that the majority of the health care services delivered in the United States are most appropriately delivered and managed by primary care physicians (HIAA, 1993). While this is not an exact description of the existing practices, it is an indicator of the importance of the primary care provider in the managed care model. The primary care physician (or nurse, physicians' assistant, or other triage personnel) determines the need for primary care and makes referrals as specialized care or hospitalization are needed, and thus controls not only the delivery of primary care but entry into other services.

However, individuals with disabilities have long been concerned about a lack of appropriate primary care, and are increasingly apprehensive about effects of capitated systems on the quantity and quality of care that will be available to them. As managed care becomes more frequent as a mechanism for delivering health care, primary care providers become even more critical to the disabled individual because of their typical roles in the managed care system, determining referrals to specialists as well as delivering primary care.

Batavia and others have written about the practice of individuals with disabilities educating primary care providers in the medical implications of their impairments, and have discussed the generally unsatisfactory nature of the primary care available to individuals with disabilities (Batavia, DeJong, Halstead, and Smith, 1989). The role of the gatekeeper—usually the primary care provider—in managed care is a critical one for individuals with disabilities. That manager not only may have an incentive to limit access to services, but also may lack competence in assessing the needs of disabled individuals with various impairments or chronic conditions.

At present, most insured individuals with disabilities are enrolled—under Medicaid or Medicare—in fee-for-service programs, where they have some latitude in choosing providers and may often elect to see rehabilitation specialists for routine and preventive care. Within this market system, it has become common for rehabilitation medicine specialists, and rehabilitation hospitals, to provide primary care. Many disabled individuals choose to return to rehabilitation specialists who are familiar with their conditions and have wide experience in the treatment of individuals with similar conditions for both routine preventive care and for treatment of occasional illnesses or injuries. Of course, not all disabled individuals seek primary care from rehabilitation specialists and teaching hospitals.

Similarly, it must be noted that not all individuals with disabilities require special health care arrangements different from those of the general population. It is also probable that special requirements of many groups of disabled individuals can be met by accommodations and attention to accessibility with mainstream programs. At present, there is no satisfactory method for identifying, or even accurately estimating the numbers of, those disabled individuals in the total population whose health care needs cannot be met through standard managed health care plans. Most studies of managed care for individuals with disabilities are based on SSI or SSDI recipients who are enrolled in Medicaid. However, Medicaid eligibility is not a satisfactory proxy for the target population of this Center, which is addressing all individuals with disabilities who require alternative health care delivery approaches. Identifying the target population based on high volume service usage is also unsatisfactory because many individuals with disabilities may use few medical services, but still require special knowledge or accommodations when they do access the health care system.

Individuals with disabilities, as potential plan enrollees, are concerned about cost containment strategies such as capitation, which have the financial incentive to deliver fewer services. There are also incentives to avoid high-risk enrollees, and to establish policies and practices that discourage the enrollment of high users. Examples of these practices discussed by Kronick (1995) in his concise description of this problem include: screening for pre-existing conditions, designing service packages to discourage potential enrollees with certain conditions, terminating of subscribers, discouraging service use by making access difficult, and encouraging disenrollment. Kronick proceeds to list a series of strategies designated to compensate for the intensely risk aversive nature of managed care programs, and these techniques are deserving of thorough evaluation in a variety of settings.

There are at present a number of alternative models for the delivery of health care services to populations with special health care needs other than the traditional fee-for-service approach. These include the social HMOs; managed care carve outs; centers of excellence and university-based medical centers; special demonstration programs that may be conducted in connection with centers for independent living or other disability organizations; designation of rehabilitation medicine specialists as primary care providers or care managers; so-called disease management models designating special elements of care based on diagnostic category; model systems of comprehensive care; special education efforts directed at primary care providers; and more traditional limited risk models based on principles of reinsurance. The suitability of these alternative models may vary by the type of impairment, age of the consumer, geographic location, and many other factors. In recent years there have been many innovative delivery models tested (Community Medical Alliance in Boston, extensively documented by Alan Meyers and Robert Masters; the On Loc project in San Francisco for elderly medically fragile and chronically ill persons; and the PACE project, for example). However, more needs to be done to investigate the applicability of a variety of models to a range of populations, especially to working age adults, to disabled individuals who are employed, and to those covered by private health insurance.

Finally, individuals with disabilities are concerned about the physical and programmatic accessibility of health care and with their own roles in maintaining health. Individuals with disabilities,. and their organizations, are learning to take an active role in the choice and management of the services they receive. Health care is one of the most critical areas for individuals with disabilities to be informed consumers. In some cases, individuals with disabilities will have a choice among benefit plans or service providers under managed care. In all cases they need the option of an informed and active role in

their individual health care, including understanding of risks and benefits, choice of optional treatments, and an opportunity to provide care systems. A second focus group identified a number of issues in managed care from the perspective of individuals with disabilities.

The primary Federal responsibility for health care services and research is with the Department of Health and Human Services (HHS). Several units of HHS, particularly the Public Health Service, the Health Care Financing Administration, and the Office of the Assistant Secretary for Planning and Evaluation (ASPE), are establishing significant programs of research into managed care for vulnerable populations. The Administration on Aging also conducts research on managed care: NIDRR plans to continue collaboration with HHS, and expects any Center funded under this priority to work closely with HHS grantees.

However, NIDRR also has had a long history of support for medical rehabilitation research and demonstrations of model systems of care. In addressing its research mission, NIDRR has been impressed by the importance of health care to rehabilitation and independence, as well as by the high value of individuals with disabilities attach to access to comprehensive, high-quality, consumer-responsive health care. In 1991, NIDRR supported a planning conference to set a long-term agenda for medical and health research in NIDRR. The conferees recommended four areas of focus: trauma care; medical rehabilitation; primary care; and long-term care.

Consistent with this agenda, NIDRR is supporting a number of RRTCs that address research issues related to trauma care, medical rehabilitation, and long-term care. In order to identify significant research issues related to primary care for individuals with disabilities, NIDRR convened a focus group of researchers, consumers, and service providers. Within the context of primary care, the group's most significant area of concern was managed care, including the role of primary care and of medical rehabilitation in the managed care system. A second focus group identified a number of issues in managed care from the perspective of individuals with disabilities.

NIDRR's funding priority on issues in managed care focuses on accessibility, consumer-responsiveness, the role of consumers and consumer organizations (e.g., Independent Living programs) in health maintenance and in the evaluation of managed care plans, and the role of rehabilitation medicine. In addition, the priority expands the target population of related research efforts that focus primarily on publicly financed systems to include individuals covered by private health plans and individuals without health care coverage. The research undertaken by this Center is expected to complement, supplement, or confirm studies sponsored by HHS.

The Secretary is interested in research that will identify the characteristics of a managed health care system that is responsive to the needs of individuals with disabilities, including research on the effects of managed care on individuals with disabilities. For the purposes of this funding priority, an individual with a disability is defined as one who has a physical or mental impairment that substantially limits one or more major life activities (Rehabilitation Act of 1973, section 7(8)(B)). One function of the funding RRTC will be to develop a definition and parameters to identify those individuals whose disabilities necessitate special health care arrangements in a managed care system.

Priority

The Secretary intends to establish an RRTC to conduct research that will contribute to the development of consumer-responsive managed health care that encompasses the continuum of care needed by individuals with disabilities whose health care needs require special attention under managed care and will provide information and training to service providers and individuals with disabilities on new developments in managed care systems and their implications for individuals with disabilities.

In addition to carrying out activities to fulfill this general purpose, the RRTC shall:

- Conduct a study assessing the impact of managed care on individuals with disabilities, by type of disability and social and demographic characteristics, examining such factors as quality of care, costs of care, access to specialty providers, service utilization, and preventive care, and develop, using the findings of this study, a method for identifying those individuals with disabilities whose health care needs require special approaches under managed care;
- Using existing data where possible, analyze alternative health delivery approaches, including carve out models, disease management models, and models combining acute and long-term services in order to: (1) identify critical elements (such as capitation formulas, incentive-rewards, or service packages) that enhance the application of traditional managed care models to individuals with disabilities; and (2) identify gaps in the data to be addressed by future research;
- Review, in cooperation with efforts sponsored by the NCQA, ASPE, and the Robert Woods Johnson Foundation, existing or emerging industry quality assurance standards in relation to the needs of individuals with disabilities, and develop and recommended quality indicators for this population, involving individuals with disabilities in this effort;
- Design, based on new or existing research about consumer training needs, and with the involvement of individuals with disabilities, programs to prepare individuals with disabilities to be educated consumers of health care, and implement these training programs, using consumer organizations in this effort;
- Serve as a center of information for policy makers, researchers, and individuals with disabilities about new developments in managed care, integrating the perspective of individuals with disabilities into the national discussion of managed care, and conduct at least two national conferences on emerging issues in research on managed care for individuals with disabilities, researchers, and service providers; and
- Establish and work with an Advisory Committee whose members include relevant Federal and other public agencies (e.g., relevant units of the Department of Health and Human Services, including ASPE, HCFA, AoA, and the Public Health Service, and the Department of Veteran's Affairs), foundations such as RWJ, key managed care representatives from the private sector, individuals with disabilities, and other NIDRR centers and projects addressing related issues.

Program Regulations: 34 CFR Parts 350 and 352.

Program Authority: 29 U.S.C. 760–762.

(Catalog of Federal Domestic Assistance Number: 84.133B, Rehabilitation Research and Training Center Program)

Dated: July 3, 1996.

Judith E. Heumann,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 96–17456 Filed 7–8–96; 8:45 am]

BILLING CODE 4000–01–P–M

DEPARTMENT OF EDUCATION

[CFDA No.: 84.133B]

Office of Special Education and Rehabilitative Services, National Institute on Disability and Rehabilitation Research; Notice Inviting Applications for a New Award Under the Rehabilitation Research and Training Center Program for Fiscal Year 1997

Purpose of Program: Rehabilitation Research and Training Centers (RRTCs) conduct coordinated and advanced programs of research on disability and rehabilitation that will produce new knowledge that will improve rehabilitation methods and service delivery systems, alleviate or stabilize disabling conditions, and promote maximum social and economic independence for individuals with disabilities. RRTCs provide training to service providers at the pre-service, in-service training, undergraduate, and graduate levels to improve the quality and effectiveness of rehabilitation services. They also provide advanced research training to individuals with disabilities and those from minority backgrounds, engaged in research on disability and rehabilitation. RRTCs serve as national and regional technical assistance resources, and provide training for service providers, individuals with disabilities and families and representatives, and rehabilitation researchers.

This notice supports the National Education Goal that calls for all Americans to possess the knowledge and skills necessary to compete in a global economy and exercise the rights and responsibilities of citizenship.

Eligible Applicants: Institutions of higher education and public or private agencies and organizations collaborating with institutions of higher education, including Indian tribes and tribal organizations, are eligible to apply for awards under this program.

Deadline for Transmittal of Applications: 9/17/96.

Application Available: 7/19/96.

Maximum Award Amount Per Year: $500,000.

Note: The Secretary will reject without consideration or evaluation any application that proposes a project funding level that exceeds the stated maximum award amount. (See 34 CFR 75.104(b) published in the Federal Register on 3/4/96 (61 FR 8454)).

Estimated Number of Awards: 1.

Note: The estimate of funding level and awards in this notice do not bind the Department of Education to a specific level of funding or number of grants.

Project Period: 60 months.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR), 34 CFR Parts 74, 75, 77, 80, 81, 82, 85, 86; (b) the regulations for this program in 34 CFR Parts 350 and 352; and (c) The priority in the notice of final priority for this program, as published elsewhere in this issue of the Federal Register, applies to this competition.

For Applications Contact: William H. Whalen, U.S. Department of Education, 600 Independence Avenue SW., Switzer Building, Room 3411, Washington, D.C. 20202. Telephone: (202) 205–9141. Individuals who use a telecommunications device for the deaf (TDD) may call the TDD number at (202) 205–8887.

FOR FURTHER INFORMATION CONTACT: Betty Jo Berland, U.S. Department of Education, 600 Independence Avenue S.W., Switzer Building, Room 3422, Washington, D.C. 20202. Telephone: (202) 205–97391. Individuals who use a telecommunications device for the deaf (TDD) may call the TDD number at (202) 205–5516. Internet: Betty—Jo—Berland@ed.gov

Information about the Department's funding opportunities, including copies of application notices for discretionary grant competitions, can be viewed on the Department's electronic bulletin board (ED Board), telephone (202) 260–9950; on the Internet Gopher Server at GOPHER.ED.GOV (under Announcements, Bulletins, and Press Releases); or on the World Wide Web at http://www.ed.gov/money.html

However, the official application notice for a discretionary grant competition is the notice published in the Federal Register.

Program Authority: 29 U.S.C. 761a and 762.

Dated: July 3, 1996.

Judith E. Heumann,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 96–17457 Filed 7–8–96; 8:45 am]

BILLING CODE 4000–01–P

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Vol. 61, No. 132

Tuesday, July 9, 1996

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Executive orders and proclamations **523–5227**

The United States Government Manual **523–5227**

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FEDERAL REGISTER PAGES AND DATES, JULY

CFR PARTS AFFECTED DURING JULY

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
6907 35083
6908 35587

Administrative Orders:

Presidential Determinations:
No. 96–36 of June 28, 1996 35075

5 CFR

Ch. XXIII 35085
Ch. LXV 36246
530 34713
531 34713
534 34713
550 34713
575 34713
581 34713
582 34713
630 34713
734 35088
2634 35589
3201 35915

Proposed Rules:
890 35973

7 CFR

58 35589
301 ..... 35102, 35107
400 34367
868 34714
946 35109
958 35592
997 35594
998 35594
1106 35596
1230 35597
1493 33825
1910 35916
1924 35916
1941 35916
1943 35916
1945 35916
1951 35916
1955 35916
1962 35916
1965 35916
1980 35916

Proposed Rules:
210 35152
220 35152
225 35152
226 35152
300 34379
319 34379
868 35687
1240 34385
1280 35982

8 CFR

103 35597
214 35934
217 35598
301 35111

Proposed Rules:
207 35984
208 35984

9 CFR

112 33840
113 33840

Proposed Rules:
1 34386
3 ..... 34386, 34389
11 34747
94 35987
301 35990
304 35990
308 35990
318 35992
319 35157
320 35990
381 ..... 35157, 35990
391 34747

10 CFR

53 35935
110 35600
205 3511
420 35890
450 35890
463 35114
1003 35112
1010 35085
1021 36222

Proposed Rules:
1021 35990

12 CFR

324 33842
367 35115
1750 35607

Proposed Rules:
207 33874
218 34749
220 33874
221 33874
250 34749
327 34751

14 CFR

1 34508
25 34716
29 33963
39 ..... 33874, 34368, 34718, 35122, 35126, 35127, 35936, 35938, 35940, 35942, 35944, 35946
61 34508
71 ..... 33843 33844, 33845, 34720, 34721, 34722, 34723, 35307
73 35623
91 34508

REMINDERS

The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

RULES GOING INTO EFFECT TODAY

AGRICULTURE DEPARTMENT
Forest Service
National Forest System timber; sale and disposal:
Federal timber contract payment modification program; published 7-9-96
Range management:
Wild free-roaming horses and burros management; correction; published 7-9-96

AGRICULTURE DEPARTMENT
Farm Service Agency
Program regulations:
Loan assessment, market placement, and seasoned direct loan borrowers graduation to loan guarantee program; published 7-9-96

AGRICULTURE DEPARTMENT
Rural Business-Cooperative Service
Program regulations:
Loan assessment, market placement, and seasoned direct loan borrowers graduation to loan guarantee program; published 7-9-96

AGRICULTURE DEPARTMENT
Rural Housing Service
Program regulations:
Loan assessment, market placement, and seasoned direct loan borrowers graduation to loan guarantee program; published 7-9-96

AGRICULTURE DEPARTMENT
Rural Utilities Service
Program regulations:
Loan assessment, market placement, and seasoned direct loan borrowers graduation to loan guarantee program; published 7-9-96

ENERGY DEPARTMENT
Federal Energy Regulatory Commission
Electric utilities (Federal Power Act):
Open access non-discriminatory transmission services provided by public utilities--
Wholesale competition promotion; stranded costs recovery by public and transmitting utilities; published 5-10-96

ENVIRONMENTAL PROTECTION AGENCY
Superfund program:
National oil and hazardous substances contingency plan--
National priorities list update; published 7-9-96

HEALTH AND HUMAN SERVICES DEPARTMENT
Food and Drug Administration
Animal drugs, feeds, and related products:
Chlortetracycline; published 7-9-96

JUSTICE DEPARTMENT
Immigration and Naturalization Service
Nonimmigrant classes:
Ports of entry accepting applications for direct transit without visa; list additions--
Oakland, CA and Sanford, FL; published 7-9-96

TRANSPORTATION DEPARTMENT
Federal Aviation Administration
Airworthiness directives:
Beech; published 6-4-96
McDonnell Douglas; published 6-4-96

COMMENTS DUE NEXT WEEK

AGRICULTURE DEPARTMENT
Agricultural Marketing Service
Apricots grown in Washington; comments due by 7-17-96; published 6-17-96
Fruits, vegetables, and other products, fresh:
Inspection, certification, and standards fee schedule; comments due by 7-15-96; published 5-14-96
Hazelnuts grown in Oregon and Washington; comments due by 7-15-96; published 6-13-96
Peanuts, domestically produced; comments due by 7-15-96; published 6-13-96

ARMS CONTROL AND DISARMAMENT AGENCY
Privacy Act; implementation; comments due by 7-16-96; published 6-13-96

COMMERCE DEPARTMENT
National Oceanic and Atmospheric Administration
Endangered and threatened species:
Sea turtle conservation; shrimp trawling requirements--
Soft turtle excluder devices approval removed, etc.; comments due by 7-15-96; published 6-17-96
Fishery conservation and management:
Atlantic surf clam and ocean quahog; comments due by 7-19-96; published 6-20-96
Gulf of Mexico and South Atlantic coastal migratory pelagic resources; comments due by 7-18-96; published 7-3-96
Ocean salmon off coasts of Washington, Oregon, and California; comments due by 7-15-96; published 7-5-96
Pacific Coast groundfish; comments due by 7-16-96; published 7-5-96
Puerto Rico and U.S. Virgin Islands reef fish; comments due by 7-15-96; published 6-17-96
Summer flounder and scup; comments due by 7-18-96; published 6-3-96
Marine mammals:
Incidental taking--
Naval activities; USS Seawolf submarine shock testing; comments due by 7-15-96; published 6-14-96

COMMERCE DEPARTMENT
National Telecommunications and Information Administration
Public telecommunications facilities program; comments due by 7-15-96; published 5-30-96

ENVIRONMENTAL PROTECTION AGENCY
Air pollutants, hazardous; national emission standards:
Surface coating operations from new or existing shipbuilding and ship repair facilities--
Compliance date revision and implementation plan submittal deadline extension; comments due by 7-18-96; published 6-18-96
Air quality implementation plans; approval and promulgation; various States:
Indiana; comments due by 7-15-96; published 6-13-96
Louisiana; comments due by 7-15-96; published 6-13-96
Virginia; comments due by 7-15-96; published 6-13-96
Clean Air Act:
State operating permits programs-
Idaho; comments due by 7-17-96; published 6-17-96
Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:
Chlorothalonil; comments due by 7-19-96; published 6-19-96
Fenarimol; comments due by 7-15-96; published 6-14-96
Quizalofop ethyl; comments due by 7-19-96; published 6-19-96
Quizalofop-p ethyl ester; comments due by 7-15-96; published 6-14-96
Sodium salt of fomesafen; comments due by 7-19-96; published 6-19-96
Triadimefon; comments due by 7-19-96; published 6-19-96
Vinyl pyrrolidone-acrylic acid copolymer; comments due by 7-15-96; published 6-14-96
Superfund program:
National oil and hazardous substances contingency plan--
National priorities list update; comments due by 7-15-96; published 6-14-96

FEDERAL COMMUNICATIONS COMMISSION
Common carrier services:
Aeronautical services provision via International Maritime Satellite Organization (Inmarsat system); comments due by 7-17-96; published 6-17-96
O+ InterLATA calls; billed party preference; comments due by 7-17-96; published 6-17-96
Satellite communications--
Application and licensing procedures; comments due by 7-15-96; published 6-24-96
Communications equipment:
Radio frequency devices--
Unlicensed NII/SUPERNet operations in 5 GHz

LIST OF PUBLIC LAWS

This is a list of public bills from the 104th Congress which have become Federal laws. It may be used in conjunction with ''P L U S'' (Public Laws Update Service) on 202–523–6641. The text of laws is not published in the **Federal Register** but may be ordered in individual pamphlet form (referred to as ''slip laws'') from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–2470).

H.R. 2803/P.L. 104–152

Anti-Car Theft Improvements Act of 1996 (July 2, 1996; 110 Stat. 1384)

S. 1136/P.L. 104–153

Anticounterfeiting Consumer Protection Act of 1996 (July 2, 1996; 110 Stat. 1386)

S. 1903/P.L. 104–154

To designate the bridge, estimated to be completed in the year 2000, that replaces the bridge on Missouri highway 74 spanning from East Cape Girardeau, Illinois, to Cape Girardeau, Missouri, as the ''Bill Emerson Memorial Bridge'', and for other purposes. (July 2, 1996; 110 Stat. 1391)

H.R. 3525/P.L. 104–155

Church Arson Prevention Act of 1996 (July 3, 1996; 110 Stat. 1392)

S. 1579/P.L. 104–156

Single Audit Act Amendments of 1996 (July 5, 1996; 110 Stat. 1396)

Last List July 3, 1996