

Friday
August 15, 1997

Federal Register

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WASHINGTON, DC

WHEN: September 9, 1997 at 9:00 am.
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

BOSTON, MA

WHEN: September 23, 1997 at 9:00 am.

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Columbia Point
Boston, MA 02125

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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.

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Notice of August 13, 1997

The President

Continuation of Emergency Regarding Export Control Regulations

On August 19, 1994, consistent with the authority provided me under the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*), I issued Executive Order 12924. In that order, I declared a national emergency with respect to the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States in light of the expiration of the Export Administration Act of 1979, as amended (50 U.S.C. App. 2401 *et seq.*). Because the Export Administration Act has not been renewed by the Congress, the national emergency declared on August 19, 1994, must continue in effect beyond August 19, 1997. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing the national emergency declared in Executive Order 12924.

This notice shall be published in the **Federal Register** and transmitted to the Congress.



THE WHITE HOUSE,
August 13, 1997.

Rules and Regulations

Federal Register

Vol. 62, No. 158

Friday, August 15, 1997

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

MERIT SYSTEMS PROTECTION BOARD

5 CFR Part 1201

Practices and Procedures

AGENCY: Merit Systems Protection Board.

ACTION: Final rule.

SUMMARY: The Board is amending its rules of practice and procedure to rescind its rule requiring dismissal of an agency's petition for review of an administrative judge's initial decision where the agency inadvertently exceeds the requirements of the judge's interim relief order. The Board will no longer dismiss the agency's petition in such a circumstance where its action was taken in good faith. The Board announced the rescission of this rule in *Silvana H. Moscato v. Department of Education*, issued November 12, 1996, and suspended the application of the rule effective from that date.

EFFECTIVE DATE: August 15, 1997.

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

SUPPLEMENTARY INFORMATION: Under 5 U.S.C. 7701(b)(2), an appellant who prevails in an appeal to the Board is entitled to the relief provided in the administrative judge's initial decision pending the outcome of any petition for review by the Board. This interim relief is to be provided effective from the date of the initial decision. Interim relief is not provided if the judge determines that it is not appropriate or if the initial decision requires the appellant's return to or presence at the workplace and the agency determines that such return or presence would be unduly disruptive. This interim relief provision was added to Title 5 of the United States Code by the Whistleblower Protection Act of 1989 (Pub. L. 101-12).

Some Federal agencies attempting to comply with an initial decision providing interim relief have cancelled the personnel action that the appellant appealed and have furnished evidence of that cancellation when filing a petition for review. From the time the interim relief provision took effect in July 1989 until November 1996, the Board consistently held that, where an agency exceeds the order for interim relief by cancelling the appealed action and thus providing final relief, the matter is effectively removed from controversy, and the agency's petition for review is rendered moot. *See, e.g., Edney v. Department of the Treasury*, 56 M.S.P.R. 248, 249-50 (1993). On June 16, 1994, the Board amended its rules of practice and procedure at 5 CFR 1201.115(b)(1) to incorporate this holding in its procedural regulations. 59 FR 30863.

In November 1996, the Board considered this issue further in its adjudication of *Silvana H. Moscato v. Department of Education*, 72 M.S.P.R. 266 (1996). In its decision in that case, the Board cited a number of appellate court decisions that declined to dismiss a case as moot even where one of the parties apparently provided relief or complied with a judgment, if the party did not intend to forego further legal proceedings. *Id.* at 6-8. In announcing its decision that it will no longer automatically dismiss an agency's petition for review as moot where the agency has inadvertently and in good faith exceeded an interim relief order, the Board stated: "We find that the Board and prudent policy are ill-served by such an automatic dismissal, where the agency attempted to comply with an order of interim relief, mistakenly exceeded the Board's requirements, did not abandon its intent to go forward, and then took steps to correct its mistake in a timely manner." *Id.* at 6.

In its decision in *Moscato*, the Board announced that it was suspending the application of the last sentence of 5 CFR 1201.115(b)(1), which required automatic dismissal of an agency's petition for review where it exceeded the requirements of an interim relief order. *Id.* at 9. The Board further stated that it would apply the new rule announced in its decision, i.e., that it would no longer dismiss an agency's petition as moot under these circumstances, in all cases relating to

the regulation at 5 CFR 1201.115(b)(1) and that it would amend its regulations to reflect the new rule. *Id.* The notice the Board publishes today makes that amendment.

The Board is publishing this rule as a final rule pursuant to 5 U.S.C. 1204(h).

List of Subjects in 5 CFR Part 1201

Administrative practice and procedure, Civil rights, Government employees.

Accordingly, the Board amends 5 CFR part 1201 as follows:

PART 1201—[AMENDED]

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

Authority: 5 U.S.C. 1204 and 7701, and 38 U.S.C. 4331, unless otherwise noted.

§ 1201.115 [Amended]

2. Section 1201.115 is amended at paragraph (b)(1) by removing the last sentence.

Dated: August 11, 1997.

Robert E. Taylor,

Clerk of the Board.

[FR Doc. 97-21647 Filed 8-14-97; 8:45 am]

BILLING CODE 7400-01-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 318

[Docket No. 95-038DF]

RIN 0583-AB97

Use of Glycerine as a Humectant in Shelf Stable Meat Snacks

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Direct final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) will permit the use of glycerine as a humectant in shelf stable meat snacks at a level not to exceed 2 percent of the formulation weight of the product. This action is being taken in response to a petition from the American Association of Meat Processors requesting use of glycerine to promote moisture retention and distribution and improved texture of shelf stable meat snacks.

DATES: This rule will be effective on October 14, 1997 unless adverse or

critical comments within the scope of the rulemaking or notice of intent to submit adverse comments within the scope of the rulemaking are received on or before September 15, 1997. If the effective date is delayed, a timely document will be published in the **Federal Register**.

ADDRESSES: Send an original and two copies of adverse written comments within the scope of the rulemaking to: FSIS Docket Clerk, DOCKET #95-038DF, Room 102, Cotton Annex, 300 12th Street, SW., Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250-3700. Data submitted by the petitioner and all comments received will be available for public inspection from 8:30 a.m. to 4:30 p.m., Monday through Friday, in the FSIS Docket Room.

FOR FURTHER INFORMATION CONTACT: Robert C. Post, Director, Facilities, Equipment, Labeling, and Compounds Review Division, (202) 418-8900.

SUPPLEMENTARY INFORMATION: FSIS was petitioned by the American Association of Meat Processors to approve the use of glycerine at a level of 3 percent in shelf stable meat snacks, i.e. products such as meat sticks that can be stored at room temperature, to promote moisture retention and distribution and improve product texture. Although 3 percent was requested, data submitted by the petitioner showed that the necessary effect could be achieved at a 2 percent level. Data reviewed showed that products containing glycerine at a level of 2 percent consistently had a lower water activity, thus inhibiting microbiological activity. These products also had improved texture.

After reviewing the petitioner's data, FSIS determined that the tables of approved substances in the Federal meat inspection regulations should be amended to allow the use of glycerine as a humectant in shelf stable meat snacks at a level not to exceed 2 percent of the formulation weight of the product. The use of glycerine under the proposed conditions will not render the product adulterated or mislead the

consumer. This is because the appearance and quality of the product will be unaffected, and the ingredient will be listed in the ingredient statement on the product label. The technical data demonstrate the efficacy of glycerine for this use. Because glycerine is generally recognized as safe (21 CFR 182.1320) when used in accordance with good manufacturing practices, the wholesomeness of the product will not be affected. Therefore, FSIS is amending the tables of approved substances in 9 CFR 318.7(c)(4) to allow the use of glycerine as a humectant in shelf stable meat snacks at a level not to exceed 2 percent of the formulation weight of the product.

FSIS expects no adverse public reaction resulting from this change in regulatory language. Therefore, unless the Agency receives adverse or critical comments within the scope of the rulemaking or a notice of intent to submit adverse comments within 30 days, the action will become final 60 days after publication in the **Federal Register**. If such adverse comments are received, the final rulemaking document will be withdrawn and a proposed rulemaking notice will be published. The proposed rulemaking notice will establish a comment period.

Executive Order 12988

This direct final rule has been reviewed under Executive Order 12988, Civil Justice Reform. In this direct final rule: (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.

Executive Order 12866 and Regulatory Flexibility Act

This final rule has been determined to be not significant and, therefore, has not been reviewed by the Office of Management and Budget.

The Administrator has made a determination that this direct final rule will not have a significant economic

impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). This direct final rule will impose no new requirements on small entities. The direct final rule will permit the use of glycerine as a humectant in shelf stable meat snacks at a level not to exceed 2 percent of the formulation weight of the product. Use of the glycerine is voluntary. Decisions by individual manufacturers on whether to use glycerine will be based on their conclusions that the benefits outweigh the implementation costs. Implementation costs would include revision of product labels.

Paperwork Requirements

The associated paperwork and recordkeeping burden hours are approved under OMB control number 0583-0092.

List of Subjects in 9 CFR Part 318

Food additives, Food packaging, Laboratories, Meat inspection, Reporting and recordkeeping requirements, Signs and symbols.

Final Rule

For the reasons discussed in the preamble, FSIS is amending 9 CFR part 318 as follows:

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

1. The authority citation for part 318 is revised to read as follows:

Authority: 7 U.S.C. 38f, 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

2. In the chart in § 318.7(c)(4), under the Class of substance "Miscellaneous," a new entry for the substance "Glycerine" is added at the end to read as follows:

§ 318.7 Approval of substances for use in the preparation of products.

* * * * *

(c) * * *

(4) * * *

Class of substance	Substance	Purpose	Products	Amount
Miscellaneous				
	Glycerine	Humectant ..	Shelf stable (Can Be stored at room temperature) meat snacks.	Not to exceed 2 percent of the formulation weight of the product in accordance with 21 CFR 182.1320

Done at Washington, DC, on: August 4, 1997.

Thomas J. Billy,
Administrator.

[FR Doc. 97-21672 Filed 8-14-97; 8:45 am]

BILLING CODE 3410-DM-U

FARM CREDIT ADMINISTRATION

12 CFR Part 650

RIN 3052-AB72

Federal Agricultural Mortgage Corporation; Receivers and Conservators

AGENCY: Farm Credit Administration.

ACTION: Final rule.

SUMMARY: The Farm Credit Administration (FCA or Agency), through the FCA Board (Board), issues a final rule amending its regulations that apply to the Federal Agricultural Mortgage Corporation (Farmer Mac or Corporation) by adding a subpart to govern a receivership or conservatorship. The final rule implements the receivership/conservatorship authorities granted to the FCA by the Farm Credit System Reform Act of 1996 (1996 Reform Act), Pub. L. 104-105 (Feb. 10, 1996) and by previous law.

DATES: This regulation shall become effective 30 days after publication in the **Federal Register** during which either or both houses of Congress are in session. Notice of the effective date will be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Larry W. Edwards, Director, Office of Secondary Market Oversight, Farm Credit Administration, McLean, VA 22102-5090, (703) 883-4051, TDD (703) 883-4444.

SUPPLEMENTARY INFORMATION: The FCA proposed amendments to its regulations governing Farmer Mac on February 24, 1997 (62 FR 8190). The 1996 Reform Act added section 8.41 to the Farm Credit Act of 1971, as amended (Act), which grants the FCA the authority to place the Corporation into receivership and expands the FCA's existing authority to place the Corporation into conservatorship. This final rule implements these statutory provisions.

Public Comments Received

The 30-day comment period expired on March 26, 1997. The FCA received three comments, one from the Corporation, one from the Farm Credit Council (FCC) on behalf of its member Farm Credit System (FCS) institutions, and one from the United States

Department of the Treasury (Treasury). The following is a discussion of the comments and FCA's responses.

A. Comments of the Farm Credit Council

Several of the FCC's comments were related to the slightly different language used in the proposed regulation compared to FCA's receivership and conservatorship regulations in part 627 of this chapter, which was the model for the proposed rule. The FCC indicated that for the most part, the differences were called to FCA's attention to make sure that they were intentional. Proposed § 650.56(b)(1) provides that a receiver of Farmer Mac may exercise all powers as are conferred upon the officers and directors of the Corporation under law and the articles and bylaws of the Corporation, while § 627.2725(b)(1) refers to powers as conferred under law and the "charter," articles, and bylaws of the institution. Although the FCA may cancel the charter of the Corporation upon the appointment of a receiver, it may also leave the charter in existence until the conclusion of the receivership. In light of this, the FCA has included the word "charter" in the final regulation. Another difference between proposed part 650 and existing part 627 of this chapter noted by the FCC is that proposed § 650.59(b) begins with a reference to the "stock and other equities of the Corporation" and concludes with a reference to payment of a liquidating dividend to Farmer Mac's "stockholders." Section 627.2735(b)(2) begins with a similar reference to "the stock and other equities" of a liquidating institution, but concludes with a reference to payment of a liquidating dividend to the "owners of such equities." The FCC believes that the reference to owners of equities is broader than the simple reference to stockholders in proposed § 650.59(b). The FCA agrees, but notes that, with respect to the Corporation, all equity owners are stockholders. Therefore, the FCA makes no change to § 650.59.

The FCC also indicated that the phrase "or applied against any indebtedness of the owners of such equities," which appears in the first sentence of paragraph (b) of proposed § 650.58, is not found in paragraph (a) of that section although the same phrase appears in both paragraphs (a) and (b) of § 627.2730. The phrase was intentionally omitted from proposed § 650.58(a) because, unlike the equity holders of Farm Credit institutions who in most cases are also borrowers of the institutions, the equity holders of the Corporation will most likely not be

indebted to the Corporation. Also, the restriction against retirement of equities in § 650.58(b) is broad enough to include applying stock against the indebtedness of the owner of the stock should any stockholders be indebted to the Corporation. As a result, the FCA omitted the phrase "or applied against any indebtedness of the owners of such equities" from § 650.58(b) of the final regulation. The final comparison to part 627 of this chapter that the FCC pointed out is that proposed § 650.65(d), like its counterpart § 627.2775(c), provides that, upon the issuance of an order placing the Corporation in conservatorship, all rights, privileges, and powers of the "members," board of directors, officers, and employees of the Corporation are vested exclusively in the conservator, and questioned whether the reference to "members" is appropriate and relevant in the case of the Corporation. The FCA agrees that the term "members" is not appropriate with reference to the Corporation and removed that term in the final regulation.

The FCC commented that the word "reasonable" should be inserted in proposed § 650.56(b)(15) immediately before the phrase "expenses of the receivership." The FCC noted in this regard that proposed § 650.61(b), concerning priority of claims, expressly limits the administrative expenses of the Corporation that may be afforded a second priority to "reasonable" expenses incurred for services actually provided by accountants, attorneys, appraisers, examiners, or management companies, or "reasonable" expenses incurred by employees that were authorized and reimbursable under a preexisting expense reimbursement policy. In response, the FCA notes that the expenses covered by § 650.61(b) are expenses of the Corporation incurred prior to the appointment of a receiver. All such expenses may not necessarily be paid, as payment is limited to the receiver's judgment that the services underlying the claims are of benefit to the receivership. In contrast, §§ 650.56(b)(15) and 650.61(a) relate only to the authority of the receiver to pay the administrative expenses of the receivership and all costs associated with carrying out the powers and duties of a receiver. Furthermore, pursuant to § 650.56(a)(3), the receiver serves as the trustee of the receivership estate and is required to conduct all of its operations, whether incurring and paying administrative expenses or exercising any other power conferred by the regulations, for the benefit of the creditors and stockholders of the Corporation. Therefore, the FCA

believes that addition of the term "reasonable" to § 650.56(b)(15) is neither necessary nor appropriate and adopts § 650.56(b)(15) as proposed.

The FCC made two comments with regard to the preamble accompanying the proposed and final regulations. The FCC asserted that during the early drafting stages of what became section 8.41 of the Act, consideration was given to authorizing a receiver of the Corporation to borrow from the Farm Credit System Insurance Fund (Insurance Fund) to meet the ongoing administrative expenses and liquidity needs of a Corporation receivership. The authorization to borrow from the Insurance Fund for such purposes was opposed by the FCS. The FCC states that, although express borrowing authority was not adopted in section 8.41, FCS institutions would take comfort from FCA's insertion, into the preamble to the final regulation, of a statement expressly acknowledging that neither section 8.41 nor the final implementing regulations authorize the Farm Credit System Insurance Corporation (FCSIC) to loan moneys from the Insurance Fund to a Corporation receiver or conservator for any reason whatsoever. In response, the FCA acknowledges the comment and notes that FCSIC's authority to make use of the Insurance Fund is governed by title V, part E of the Act, not FCA regulations.

The other comment regarding the preamble to the proposed regulation points out that the preamble states that the Corporation will be required to comply with the applicable provisions of the Securities Act of 1933 and the Securities Exchange Act of 1934, but proposed § 650.67(c), while expressly referring to the requirements of § 620.40 and part 621 of this chapter, makes no reference to the securities acts. The FCC questioned whether the omission was intentional or inadvertent. The FCA notes that § 620.40 and part 621 of this chapter require the Corporation to comply with the securities acts, and the statement in the preamble was merely a reference to the requirement. Therefore, the FCA makes no change to § 650.67.

B. Federal Agricultural Mortgage Corporation Comments

The Corporation commented on § 650.50 of the proposed regulation, which provides the grounds for which a receiver may be appointed for the Corporation, and requested that the FCA amend § 650.50(a)(1) to clarify the definition of insolvency. Under the proposed regulation, the Corporation would be considered insolvent if its assets are less than its obligations to its

creditors and others or if the Corporation is unable to pay its debts in the ordinary course of business. In relation to the first criterion, the Corporation guarantees mortgage-backed securities that are sold to third-party entities or individuals and then classified for accounting purposes as "off-balance-sheet" contingent liabilities of the guarantor. Because there is no definition of the word "obligations" in the Act, in the proposed regulations, or in the regulations contained in part 627 of this chapter, the Corporation questions whether obligations would include contingent liabilities, particularly guarantees. The Corporation asserts that if obligations are interpreted to include the contingent liabilities of the Corporation as a guarantor of securities pursuant to its authorities under the Act, it could be deemed to be insolvent today, which would not be a result intended by Congress or reflective of the Corporation's true financial condition. The amendment to § 650.50 suggested by the Corporation would expressly exclude contingent liabilities under guarantees issued by the Corporation. Alternatively, the Corporation commented that if the FCA intended to include contingent liabilities as obligations for the purposes of determining insolvency, the value of the liabilities should be adjusted based upon an assessment of the probability that the contingency of default will occur and that the Corporation will be called upon to pay under its guarantee and should be net of the reserves for losses of the Corporation. Further, the assets of the Corporation should include the value of any rights that the Corporation would have against any other parties in the event that it is called upon to pay on a guarantee, including, but not limited to, rights of subrogation or reimbursement from a primary obligor. The Corporation provided suggested regulatory language to implement the two alternatives.

The FCA does not believe that contingent liabilities of the Corporation as a guarantor of securities pursuant to its authorities under the Act would ordinarily be considered as obligations for purposes of determining the Corporation's solvency under § 650.50(a)(1)(i). A loss contingency related to such guarantees would affect the determination of solvency (and would likely be recorded in the Corporation's financial statements) if a loss were probable and could be reasonably estimated. Moreover, if a loss contingency were both probable and could be reasonably estimated, the amount of such contingency that would

be included in the determination of solvency would be based on an analysis of the circumstances and would not necessarily be the amount of the guarantee itself. The treatment of contingent liabilities for the purposes of § 650.50(a)(1)(i) is consistent with the treatment of contingent liabilities under Generally Accepted Accounting Principles, specifically, Statement of Financial Accounting Standards No. 5, Accounting for Contingencies (SFAS No. 5). SFAS No. 5 requires that an estimated loss from a loss contingency be recorded in the financial statements if it is both probable that a liability has been incurred at the date of the financial statements and the amount of the loss can be reasonably estimated. If a loss contingency is not recorded in the financial statements because one or both of the above criteria are not met, disclosure of the loss contingency may or may not be required depending on the likelihood that a loss will be incurred. Disclosure of contingencies in such circumstances, however, is made in management's discussion and analysis and the contingencies are not recorded as liabilities in the financial statements.

Because the FCA generally would not consider the Corporation's contingent guarantee obligations to be included in the calculation of insolvency unless a liability related to such guarantees was probable and could be reasonably estimated, the FCA has not amended § 650.50(a)(1)(i) in the manner suggested by the commenter. A blanket exclusion of such obligations would not be appropriate because it could serve to confuse rather than clarify the requirements of the regulation. Further, the FCA believes that it is unlikely that investors would mistakenly conclude that all of the Corporation's contingent guarantee obligations would be included in the FCA's calculation of insolvency because the treatment of contingent liabilities is a generally widespread and well-known concept. As a final note, although the FCA generally would not include the amount of the contingent guarantee obligations in the calculation of insolvency for the purpose of these regulations, the Corporation's general ability to meet its contingent guarantee obligations are considered by the FCA when making any determination concerning the safety and soundness of the Corporation.

The Corporation also commented regarding § 650.60(b) of the proposed regulation, which authorizes a receiver of the Corporation to allow any claim that is timely received and proved to the receiver's satisfaction. The receiver also has the power to disallow claims in

whole or in part if not proved to the receiver's satisfaction. The disallowance is final unless, within 30 days, a claimant files a written request for payment regardless of the disallowance. Any such request is reconsidered by the receiver, who may approve or disapprove the claim in whole or in part. The Corporation requested that the FCA amend § 650.60 to provide that the FCA (through an official of the FCA who did not participate in the initial disallowance of the claim) would reconsider a disallowed claim upon the request of a claimant in order to ensure that a disallowed claim would be reviewed by an entity other than the person who initially disallowed the claim. In addition, the Corporation asserts that such an amendment would ultimately make decisions regarding the allowance of claims reviewable under the provisions of the Administrative Procedure Act (APA), 5 U.S.C. 500 *et seq.*, with all of its procedural safeguards, including the availability of judicial review. The Corporation contends that it is important for investors and others who do business with it to know that, in the unlikely event that a receiver were to be appointed, procedures regarding the recognition of their claims would be fair, and any disallowance of their claims would be subject to review by the FCA.

The FCA does not believe it is appropriate for it to review claims disallowed by the receiver and has not amended § 650.60. Unless the FCA, pursuant to section 8.41(c) of the Act, is the receiver of the Corporation, the FCA will ordinarily leave administrative decisions to the judgment of the receiver. FCA's regulations under part 627 of this chapter do not provide for the Agency's review of claim denial decisions, and the FCA does not believe it is appropriate to afford different treatment to the creditors of the Corporation. Further, these regulations do not preclude any other avenues of review that may be available to a claim holder.

C. Treasury Comments

In the preamble discussion accompanying proposed § 650.56(b), the FCA noted that generally, a receiver or conservator of the Corporation would have all of the rights and powers that the Corporation had prior to the appointment of the receiver and requested comment on whether there should be any limits imposed on these powers. The Treasury commented that because the purpose of a receivership would be to wind up the Corporation's affairs, the receiver should not be

conducting new business, such as issuing guarantees, or expanding the Corporation's debt obligations. The power of a receiver to exercise all powers that are conferred upon the Corporation is not intended to allow the receiver to search out or engage in new business opportunities. The power of the receiver to issue guarantees, debt obligations, or any other authority of the Corporation is designed to enable the receiver to conclude any transactions that were in progress when the receiver was appointed or take other similar actions if such actions are in the best interest of the receivership. Restricting the receiver's powers to less than those of the Corporation may preclude the receiver from acting in the best interest of the receivership. Therefore, the FCA is making no change as a result of this comment.

D. Section 650.61—Priority of Claims

The Corporation, the FCC, and the Treasury commented with regard to § 650.61, which establishes the priority for payment of claims against the Corporation in receivership. The Corporation commented that proposed § 650.61 did not explicitly provide a priority for claims of holders of securities guaranteed by the Corporation (guaranteed securities). Further, the Corporation asserts that because investors in guaranteed securities rely in part on the right of Farmer Mac to sell obligations to the Secretary of the Treasury (12 U.S.C. 2279aa–13), any inference in the regulations that the claims of holders would not take precedence over the claims of general creditors could create uncertainty with respect to the Corporation's guarantee and adversely affect the market for, and pricing of, its guaranteed securities. The Corporation recommended that the FCA amend § 650.61 to provide for payment of claims of holders of guaranteed securities prior to the payment of general, unsecured creditors.

The FCA has not adopted this suggestion because the Act does not provide a priority in liquidation for holders of guaranteed securities over other creditors of the Corporation. In addition, holders of guaranteed securities already have significant protection. They have direct access to the assets of the specific pool securing their securities as well as the guarantee of the Corporation should the assets backing the pool not be sufficient. Further, the Corporation has borrowing authority from Treasury to help enable it to fulfill guarantees.

In the preamble to the proposed regulation, the FCA stated that it was considering whether to provide a

priority over other creditors for obligations issued to the Treasury and requested comment on the issue. The FCC commented that the obligations issued to the Treasury should have a priority over other creditors only if one is provided by statute. The Corporation commented that because the statute does not provide a priority for obligations issued to the Treasury, no such priority should be provided by regulation. Further, the Corporation asserted that giving a priority position for the Treasury over other unsecured general creditors of the Corporation could adversely affect its dealings with vendors who would be general creditors in the unlikely event of a receivership. The Treasury requested that the regulations provide a priority over unsecured general creditors for any unsecured Farmer Mac obligations issued to the Treasury.

The FCA believes that any priority afforded to the Corporation's obligations should be determined by statute and the terms of the obligations. The FCA notes that other statutes may provide some protection to the Treasury, but the Act does not provide a priority in liquidation for obligations issued to the Treasury. Therefore, the FCA has not included such a priority in § 650.61. Obligations issued to the Secretary of the Treasury will be paid in the class of secured or unsecured creditors, depending on the nature of the obligations.

Other than the changes previously noted to §§ 650.56, 650.58, and 650.65, and minor editorial changes, the FCA adopts the amendments to part 650 as proposed.

List of Subjects in 12 CFR Part 650

Agriculture, Banks, banking, Conflicts of interests, Rural areas.

For the reasons stated in the preamble, part 650 of chapter VI, title 12 of the Code of Federal Regulations is amended to read as follows:

PART 650—FEDERAL AGRICULTURAL MORTGAGE CORPORATION

1. The authority citation for part 650 is revised to read as follows:

Authority: Secs. 4.12, 5.9, 5.17, 8.11, 8.37, 8.41 of the Farm Credit Act (12 U.S.C. 2183, 2243, 2252, 2279aa–11, 2279bb–6, 2279cc); sec. 514 of Pub. L. 102–552, 106 Stat. 4102; sec. 118 of Pub. L. 104–105, 110 Stat. 168.

2. Part 650 is amended by adding a new subpart C to read as follows:

Subpart C—Receiver and Conservator

Sec.

- 650.50 Grounds for appointment of a receiver or conservator.
- 650.51 Action for removal of receiver or conservator.
- 650.52 Voluntary liquidation.
- 650.55 Appointment of a receiver.
- 650.56 Powers and duties of the receiver.
- 650.57 Report to Congress.
- 650.58 Preservation of equity.
- 650.59 Notice to stockholders.
- 650.60 Creditor claims.
- 650.61 Priority of claims.
- 650.62 Payment of claims.
- 650.63 Inventory, audit, and reports.
- 650.64 Final discharge and release of the receiver.
- 650.65 Appointment of a conservator.
- 650.66 Powers and duties of the conservator.
- 650.67 Inventory, examination, and reports to stockholders.
- 650.68 Final discharge and release of the conservator.

Subpart C—Receiver and Conservator**§ 650.50 Grounds for appointment of a receiver or conservator.**

(a) The grounds for the appointment of a receiver or conservator for the Corporation are:

(1) The Corporation is insolvent. For purposes of this paragraph, insolvent means:

(i) The assets of the Corporation are less than its obligations to its creditors and others; or

(ii) The Corporation is unable to pay its debts as they fall due in the ordinary course of business;

(2) There has been a substantial dissipation of the assets or earnings of the Corporation due to the violation of any law, rule, or regulation, or the conduct of an unsafe or unsound practice;

(3) The Corporation is in an unsafe or unsound condition to transact business;

(4) The Corporation has committed a willful violation of a final cease-and-desist order issued by the Farm Credit Administration Board;

(5) The Corporation is concealing its books, papers, records, or assets, or is refusing to submit its books, papers, records, assets, or other material relating to the affairs of the Corporation for inspection to any examiner or any lawful agent of the Farm Credit Administration Board.

(b) In addition to the grounds set forth in paragraph (a) of this section, a receiver can be appointed for the Corporation if the Farm Credit Administration Board determines that the appointment of a conservator would not be appropriate when one of the following conditions exists:

(1) The authority of the Corporation to purchase qualified loans or issue or

guarantee loan-backed securities is suspended; or

(2) The Corporation is classified under section 8.35 of the Act as within enforcement level III or IV and the alternative actions available under subtitle B of title VIII of the Act are not satisfactory.

(c) In addition to the grounds set forth in paragraph (a) of this section, a conservator can be appointed for the Corporation if:

(1) The Corporation is classified under section 8.35 of the Act as within enforcement level III or IV; or

(2) The authority of the Corporation to purchase qualified loans or issue or guarantee loan-backed securities is suspended.

§ 650.51 Action for removal of receiver or conservator.

Upon the appointment of a receiver or conservator for the Corporation by the Farm Credit Administration Board pursuant to § 650.50 of this subpart, the Corporation may, within 30 days of such appointment, bring an action in the United States District Court for the District of Columbia, for an order requiring the Farm Credit Administration Board to remove the receiver or conservator and, if the charter has been canceled, to rescind the cancellation of the charter. Notwithstanding any other provision of this part, the Corporation's board of directors is empowered to meet subsequent to such appointment and authorize the filing of an action for removal. An action for removal may be authorized only by the Corporation's board of directors.

§ 650.52 Voluntary liquidation.

(a) The Corporation may voluntarily liquidate by a resolution of its board of directors, but only with the consent of, and in accordance with a plan of liquidation approved by, the Farm Credit Administration Board. Upon adoption of such resolution, the Corporation shall submit the resolution and proposed voluntary liquidation plan to the Farm Credit Administration Board for preliminary approval. The Farm Credit Administration Board, in its discretion, may appoint a receiver as part of an approved liquidation plan. If a receiver is appointed for the Corporation as part of a voluntary liquidation, the receivership shall be conducted pursuant to the regulations of this part, except to the extent that an approved plan of liquidation provides otherwise.

(b) If the Farm Credit Administration Board gives preliminary approval to the liquidation plan, the board of directors

of the Corporation shall submit the resolution to liquidate to the stockholders for a vote in accordance with the bylaws of the Corporation.

(c) The Farm Credit Administration Board will consider final approval of the resolution to voluntarily liquidate and the liquidation plan after an affirmative stockholder vote on the resolution.

§ 650.55 Appointment of a receiver.

(a) The Farm Credit Administration Board may in its discretion appoint, ex parte and without prior notice, a receiver for the Corporation provided that one or more of the grounds for appointment as set forth in § 650.50 of this subpart exist.

(b) Upon the appointment of the receiver, the Chairman of the Farm Credit Administration Board shall immediately notify the Corporation and shall publish a notice of the appointment in the **Federal Register**.

(c) Upon the issuance of the order placing the Corporation into liquidation and appointing the receiver, all rights, privileges, and powers of the board of directors, officers, and employees of the Corporation shall be vested exclusively in the receiver. The Farm Credit Administration Board may cancel the charter of the Corporation on such date as the Farm Credit Administration Board determines is appropriate, but not later than the conclusion of the receivership and discharge of the receiver.

§ 650.56 Powers and duties of the receiver.

(a) *General.* (1) Upon appointment as receiver, the receiver shall take possession of the Corporation in order to wind up the business operations of the Corporation, collect the debts owed to the Corporation, liquidate its property and assets, pay its creditors, and distribute the remaining proceeds to stockholders. The receiver is authorized to exercise all powers necessary to the efficient termination of the Corporation's operation as provided for in this part.

(2) Upon its appointment as receiver, the receiver automatically succeeds to:

(i) All rights, titles, powers, and privileges of the Corporation and of any stockholder, officer, or director of the Corporation with respect to the Corporation and the assets of the Corporation; and

(ii) Title to the books, records, and assets of the Corporation in the possession of any other legal custodian of the Corporation.

(3) The receiver of the Corporation serves as the trustee of the receivership estate and conducts its operations for

the benefit of the creditors and stockholders of the Corporation.

(b) *Specific powers.* The receiver may:

(1) Exercise all powers as are conferred upon the officers and directors of the Corporation under law and the charter, articles, and bylaws of the Corporation.

(2) Take any action the receiver considers appropriate or expedient to carry on the business of the Corporation during the process of liquidating its assets and winding up its affairs.

(3) Borrow funds in accordance with section 8.41(f) of the Act to meet the ongoing administrative expenses or other liquidity needs of the receivership.

(4) Pay any sum the receiver deems necessary or advisable to preserve, conserve, or protect the Corporation's assets or property or rehabilitate or improve such property and assets.

(5) Pay any sum the receiver deems necessary or advisable to preserve, conserve, or protect any asset or property on which the Corporation has a lien or in which the Corporation has a financial or property interest, and pay off and discharge any liens, claims, or charges of any nature against such property.

(6) Investigate any matter related to the conduct of the business of the Corporation, including, but not limited to, any claim of the Corporation against any individual or entity, and institute appropriate legal or other proceedings to prosecute such claims.

(7) Institute, prosecute, maintain, defend, intervene, and otherwise participate in any legal proceeding by or against the Corporation or in which the Corporation or its creditors or stockholders have any interest, and represent in every way the Corporation, its stockholders and creditors.

(8) Employ attorneys, accountants, appraisers, and other professionals to give advice and assistance to the receivership generally or on particular matters, and pay their retainers, compensation, and expenses, including litigation costs.

(9) Hire any agents or employees necessary for proper administration of the receivership.

(10) Execute, acknowledge, and deliver, in person or through a general or specific delegation, any instrument necessary for any authorized purpose, and any instrument executed under this paragraph shall be valid and effective as if it had been executed by the Corporation's officers by authority of its board of directors.

(11) Sell for cash or otherwise any mortgage, deed of trust, chose in action, note, contract, judgment or decree,

stock, or debt owed to the Corporation, or any property (real or personal, tangible or intangible).

(12) Purchase or lease office space, automobiles, furniture, equipment, and supplies, and purchase insurance, professional, and technical services necessary for the conduct of the receivership.

(13) Release any assets or property of any nature, regardless of whether the subject of pending litigation, and repudiate, with cause, any lease or executory contract the receiver considers burdensome.

(14) Settle, release, or obtain release of, for cash or other consideration, claims and demands against or in favor of the Corporation or receiver.

(15) Pay, out of the assets of the Corporation, all expenses of the receivership (including compensation to personnel employed to represent or assist the receiver) and all costs of carrying out or exercising the rights, powers, privileges, and duties as receiver.

(16) Pay, out of the assets of the Corporation, all approved claims of indebtedness in accordance with the priorities established in this part.

(17) Take all actions and have such rights, powers, and privileges as are necessary and incident to the exercise of any specific power.

(18) Take such actions, and have such additional rights, powers, privileges, immunities, and duties as the Farm Credit Administration Board authorizes by order or by amendment of any order or by regulation.

§ 650.57 Report to Congress.

On a determination by the receiver that there are insufficient assets of the receivership to pay all valid claims against the receivership, the receiver shall submit to the Secretary of the Treasury and Congress a report on the financial condition of the receivership.

§ 650.58 Preservation of equity.

(a) Except as provided for upon final distribution of the assets of the Corporation pursuant to § 650.62 of this subpart, no capital stock, equity reserves, or other allocated equities of the Corporation in receivership shall be issued, allocated, retired, sold, distributed, transferred, or assigned.

(b) Immediately upon the adoption of a resolution by its board of directors to voluntarily liquidate the Corporation, the capital stock, equity reserves, and allocated equities of the Corporation shall not be issued, allocated, retired, sold, distributed, transferred, or assigned. Such activities could resume if the stockholders of the Corporation or

the Farm Credit Administration Board disapprove the resolution. In the event the resolution is approved by the stockholders of the Corporation and the Farm Credit Administration Board, the liquidation plan shall govern disposition of the equities of the Corporation as provided in § 650.52 of this subpart.

§ 650.59 Notice to stockholders.

As soon as practicable after a receiver takes possession of the Corporation, the receiver shall notify, by first class mail, each holder of stock of the following matters:

(a) The number of shares such holder owns;

(b) That the stock and other equities of the Corporation may not be retired or transferred until the liquidation is completed, whereupon the receiver will distribute a liquidating dividend, if any, to the stockholders; and

(c) Such other matters as the receiver or the Farm Credit Administration Board deems necessary.

§ 650.60 Creditor claims.

(a) Upon appointment, the receiver shall promptly publish a notice to creditors to present their claims against the Corporation, with proof thereof, to the receiver by a date specified in the notice, which shall be not less than 90 calendar days after the first publication. The notice shall be republished approximately 30 days and 60 days after the first publication. The receiver shall promptly send, by first class mail, a similar notice to any creditor shown on the Corporation's books at the creditor's last address appearing thereon. Claims filed after the specified date shall be disallowed except as the receiver may approve them for full or partial payment from the Corporation's assets remaining undistributed at the time of approval.

(b) The receiver shall allow any claim that is timely received and proved to the receiver's satisfaction. The receiver may disallow in whole or in part any creditor's claim or claim of security, preference, or priority that is not proved to the receiver's satisfaction or is not timely received and shall notify the claimant of the disallowance and reason therefor. Sending the notice of disallowance by first class mail to the claimant's address appearing on the proof of claim shall be sufficient notice. The disallowance shall be final unless, within 30 days after the notice of disallowance is mailed, the claimant files a written request for payment regardless of the disallowance. The receiver shall reconsider any claim upon the timely request of the claimant

and may approve or disapprove such claim in whole or in part.

(c) Creditors' claims that are allowed shall be paid by the receiver from time to time, to the extent funds are available therefor and in accordance with the priorities established in this part and in such manner and amounts as the receiver deems appropriate. In the event the Corporation has a claim against a creditor of the Corporation, the receiver shall offset the amount of such claim against the claim asserted by such creditor.

§ 650.61 Priority of claims.

The following priority of claims shall apply to the distribution of the assets of the Corporation in liquidation:

(a) All costs, expenses, and debts incurred by the receiver in connection with the administration of the receivership, all Farm Credit Administration assessments for the costs of supervising and examining the Corporation, and any amounts borrowed pursuant to § 650.56(b)(3).

(b) Administrative expenses of the Corporation, provided that such expenses were incurred within 60 days prior to the receiver's taking possession, and that such expenses shall be limited to reasonable expenses incurred for services actually provided by accountants, attorneys, appraisers, examiners, or management companies, or reasonable expenses incurred by employees that were authorized and reimbursable under a preexisting expense reimbursement policy and that, in the opinion of the receiver, are of benefit to the receivership, and shall not include wages or salaries of employees of the Corporation.

(c) If authorized by the receiver, claims for wages and salaries, including vacation pay, earned prior to the appointment of the receiver by an employee of the Corporation whom the receiver determines it is in the best interest of the receivership to engage or retain for a reasonable period of time.

(d) If authorized by the receiver, claims for wages and salaries, including vacation pay, earned prior to the appointment of the receiver, up to a maximum of three thousand dollars (\$3,000) per person as adjusted for inflation, by an employee of the Corporation not engaged or retained by the receiver. The adjustment for inflation shall be the percentage by which the Consumer Price Index (as prepared by the Department of Labor) for the calendar year preceding the appointment of the receiver exceeds the Consumer Price Index for the calendar year 1992.

(e) All claims for taxes.

(f) All claims of creditors which are secured by specific assets of the Corporation, with priority of conflicting claims of creditors within this same class to be determined in accordance with priorities of applicable Federal or State law.

(g) All claims of general creditors.

§ 650.62 Payment of claims.

(a) All claims of each class described in § 650.61 of this subpart shall be paid in full or provisions shall be made for such payment prior to the payment of any claim of a lesser priority. If there are insufficient funds to pay all claims in a class in full, distribution to that class will be on a pro rata basis.

(b) Following the payment of all claims, the receiver shall distribute the remainder of the assets of the Corporation, if any, to the owners of stock and other equities in accordance with the priorities for impairment set forth in section 8.4(e)(3) of the Act and the bylaws of the Corporation.

§ 650.63 Inventory, audit, and reports.

(a) As soon as practicable after taking possession of the Corporation, the receiver shall take an inventory of the assets and liabilities as of the date possession was taken.

(b) The receivership shall be audited on an annual basis by a certified public accountant selected by the receiver.

(c) The receiver shall make an annual accounting or report, as appropriate, available for review upon request to any stockholder of the Corporation or any member of the public, with a copy provided to the Farm Credit Administration.

(d) As soon as practicable after final distribution, the receiver shall send to each stockholder of record a report summarizing the disposition of the assets of the receivership and claims against the receivership.

§ 650.64 Final discharge and release of the receiver.

After the receiver has made a final distribution of the assets of the receivership, the receivership shall be terminated, the charter shall be canceled by the Farm Credit Administration Board if such cancellation has not previously occurred, and the receiver shall be finally discharged and released.

§ 650.65 Appointment of a conservator.

(a) The Farm Credit Administration Board may in its discretion appoint, ex parte and without prior notice, a conservator for the Corporation provided that one or more of the grounds for appointment as set forth in § 650.50 of this subpart exist;

(b) Upon the appointment of a conservator, the Chairman of the Farm Credit Administration shall immediately notify the Corporation and shall publish a notice of the appointment in the **Federal Register**.

(c) As soon as practicable after the conservator takes possession of the Corporation, the conservator shall notify, by first class mail, each holder of stock in the Corporation of the establishment of the conservatorship and shall describe the effect of the conservatorship on the Corporation's operations and equity holdings.

(d) Upon the issuance of the order placing the Corporation in conservatorship, all rights, privileges, and powers of the board of directors, officers, and employees of the Corporation are vested exclusively in the conservator.

(e) The Farm Credit Administration Board may, at any time, terminate the conservatorship and direct the conservator to turn over the Corporation's operations to such management as the Farm Credit Administration Board may designate, in which event the provisions of this subpart shall no longer apply.

§ 650.66 Powers and duties of the conservator.

(a) The conservator shall direct the Corporation's further operation until the Farm Credit Administration Board decides that the Corporation can operate without the conservatorship or places the Corporation into receivership. Upon correction or resolution of the problem or condition that provided the basis for the appointment, the Farm Credit Administration Board may turn the Corporation over to such management as the Farm Credit Administration Board may direct.

(b) The conservator shall exercise all powers necessary to continue the ongoing operations of the Corporation, to conserve and preserve the Corporation's assets and property, and otherwise protect the interests of the Corporation, its stockholders, and creditors as provided in this subpart.

(c) The conservator serves as the trustee of the Corporation and conducts its operations for the benefit of the creditors and stockholders of the Corporation.

(d) The conservator may exercise the powers that a receiver of the Corporation may exercise under any of the provisions of § 650.56(b) of this subpart, except paragraphs (b)(2) and (b)(16). In interpreting the applicable paragraphs for purposes of this section, the terms "conservator" and

“conservatorship” shall be read for “receiver” and “receivership”.

(e) The conservator may also take any other action the conservator considers appropriate or expedient to the continuing operation of the Corporation.

§ 650.67 Inventory, examination, and reports to stockholders.

(a) As soon as practicable after taking possession of the Corporation, the conservator shall take an inventory of the assets and liabilities of the Corporation as of the date possession was taken. One copy of the inventory shall be filed with the Farm Credit Administration.

(b) The conservatorship shall be examined by the Farm Credit Administration in accordance with section 8.11 of the Act.

(c) The conservatorship shall prepare and file financial reports and other documents in accordance with the requirements of § 620.40 and part 621 of this chapter. The conservator of the Corporation shall provide the certification required in § 621.14 of this chapter.

§ 650.68 Final discharge and release of the conservator.

At such time as the conservator shall be relieved of its conservatorship duties, the conservator shall file a report on the conservator's activities with the Farm Credit Administration. The conservator shall thereupon be completely and finally released.

Dated: August 7, 1997.

Floyd Fithian,

Secretary, Farm Credit Administration Board.

[FR Doc. 97-21671 Filed 8-14-97; 8:45 am]

BILLING CODE 6705-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

New Drug Applications and Abbreviated New Drug Applications; Editorial Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its new drug application (NDA) and abbreviated new drug application (ANDA) regulations to reflect a reorganization in the Center for Drug Evaluation and Research (CDER). This action will improve the accuracy of the regulations.

EFFECTIVE DATE: August 15, 1997.

FOR FURTHER INFORMATION CONTACT:

Olivia A. Vieira, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: FDA is amending its NDA and ANDA regulations to reflect a reorganization in CDER. The name of the former Division of Regulatory Affairs (HFD-360) has been changed to the Regulatory Policy Staff (HFD-7). Furthermore, the division is no longer part of the Office of Compliance and now reports to the Associate Director for Policy (HFD-5). The regulations are being amended in 21 CFR 314.110 (a)(3) and (b), 314.120(a)(3), and 314.440(a)(3) to reflect this change.

Publication of this document constitutes final action on these changes under the Administrative Procedures Act (5 U.S.C. 553). Because the amendments are wholly editorial and nonsubstantive in nature, FDA finds that notice and public procedure are unnecessary.

List of Subjects in 21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 314 is amended as follows:

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG

1. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701, 704, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371, 374, 379e).

§ 314.110 [Amended]

2. Section 314.110 Approvable letter to the applicant is amended in paragraphs (a)(3) and (b) by removing the phrase “Division of Regulatory Affairs (HFD-360)” and adding in its place the phrase “Associate Director for Policy (HFD-5)”.

§ 314.120 [Amended]

3. Section 314.120 Not approvable letter to the applicant is amended in paragraph (a)(3) by removing the phrase “Division of Regulatory Affairs (HFD-360)” and adding in its place the phrase “Associate Director for Policy (HFD-5)”.

§ 314.440 [Amended]

4. Section 314.440 Addresses for applications and abbreviated applications is amended in paragraph (a)(3) by removing the phrase “Division of Regulatory Affairs (HFD-360)” and adding in its place the phrase “Associate Director for Policy (HFD-5)”.

Dated: August 8, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97-21649 Filed 8-14-97; 8:45 am]

BILLING CODE 4160-01-M

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4044

Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: The Pension Benefit Guaranty Corporation's regulation on Allocation of Assets in Single-Employer Plans prescribes interest assumptions for valuing benefits under terminating single-employer plans. This final rule amends the regulation to adopt interest assumptions for plans with valuation dates in September 1997.

EFFECTIVE DATE: September 1, 1997.

FOR FURTHER INFORMATION CONTACT:

Harold J. Ashner, Assistant General Counsel, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202-326-4024 (202-326-4179 for TTY and TDD).

SUPPLEMENTARY INFORMATION: The PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) prescribes actuarial assumptions for valuing plan benefits of terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974.

Among the actuarial assumptions prescribed in part 4044 are interest assumptions. These interest assumptions are intended to reflect current conditions in the financial and annuity markets.

Two sets of interest assumptions are prescribed, one set for the valuation of benefits to be paid as annuities and one set for the valuation of benefits to be paid as lump sums. This amendment adds to appendix B to part 4044 the annuity and lump sum interest assumptions for valuing benefits in

plans with valuation dates during September 1997.

For annuity benefits, the interest assumptions will be 5.70 percent for the first 25 years following the valuation date and 5.00 percent thereafter. The annuity interest assumptions represent a decrease (from those in effect for August 1997) of 0.40 percent for the first 25 years following the valuation date and are otherwise unchanged. For benefits to be paid as lump sums, the interest assumptions to be used by the PBGC will be 4.50 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. The lump sum interest assumptions represent a decrease (from those in effect for August 1997) of 0.25 percent for the period during which a benefit is in pay status; they are otherwise unchanged.

The PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect, as accurately as possible, current market conditions.

Because of the need to provide immediate guidance for the valuation of benefits in plans with valuation dates during September 1997, the PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

The PBGC has determined that this action is not a "significant regulatory action" under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this

amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects in 29 CFR Part 4044

Pension insurance, Pensions.

In consideration of the foregoing, 29 CFR part 4044 is amended as follows:

PART 4044—ALLOCATION OF ASSETS IN SINGLE-EMPLOYER PLANS

1. The authority citation for part 4044 continues to read as follows:

Authority: 29 U.S.C. 1301(a), 1302(b)(3), 1341, 1344, 1362.

2. In appendix B, a new entry is added to Table I, and Rate Set 47 is added to Table II, as set forth below. The introductory text of each table is republished for the convenience of the reader and remains unchanged.

APPENDIX B TO PART 4044—INTEREST RATES USED TO VALUE ANNUITIES AND LUMP SUMS

TABLE I.—ANNUITY VALUATIONS

[This table sets forth, for each indicated calendar month, the interest rates (denoted by i_1 , i_2 , * * *, and referred to generally as i_t) assumed to be in effect between specified anniversaries of a valuation date that occurs within that calendar month; those anniversaries are specified in the columns adjacent to the rates. The last listed rate is assumed to be in effect after the last listed anniversary date]

For valuation dates occurring in the month—			The values of i_t are:					
			i_t	for $t=$	i_t	for $t=$	i_t	for $t=$
*	*	*	*	*	*	*	*	*
September 1997			.0570	1–25	.0500	>25	N/A	N/A

TABLE II.—LUMP SUM VALUATIONS

[In using this table: (1) For benefits for which the participant or beneficiary is entitled to be in pay status on the valuation date, the immediate annuity rate shall apply; (2) For benefits for which the deferral period is y years (where y is an integer and $0 < y \leq n_1$), interest rate i_1 shall apply from the valuation date for a period of y years, and thereafter the immediate annuity rate shall apply; (3) For benefits for which the deferral period is y years (where y is an integer and $n_1 < y \leq n_1 + n_2$), interest rate i_2 shall apply from the valuation date for a period of $y - n_1$ years, interest rate i_1 shall apply for the following n_1 years, and thereafter the immediate annuity rate shall apply; (4) For benefits for which the deferral period is y years (where y is an integer and $y > n_1 + n_2$), interest rate i_3 shall apply from the valuation date for a period of $y - n_1 - n_2$ years, interest rate i_2 shall apply for the following n_2 years, interest rate i_1 shall apply for the following n_1 years, and thereafter the immediate annuity rate shall apply]

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)					
	On or after	Before		i_1	i_2	i_3	n_1	n_2	
*	*	*	*	*	*	*	*	*	*
47	09–1–97	10–1–97	4.50	4.00	4.00	4.00	7	8	

Issued in Washington, D.C., on this 8th day of August 1997.

David M. Strauss,

Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 97-21599 Filed 8-14-97; 8:45 am]

BILLING CODE 7708-01-P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD07-97-031]

RIN 2115-AE46

Special Local Regulations: Hurricane Offshore Classic, St. Petersburg, FL

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing permanent special local regulations for the Hurricane Offshore Classic. This event will be held annually during the third Saturday and Sunday of August, between 11 a.m. and 5 p.m. Eastern Daylight Time (EDT). There will be approximately 400 participants and spectator craft. The resulting congestion of navigable channels creates an extra or unusual hazard in the navigable waters. These regulations are necessary to provide for the safety of life on navigable waters during the event.

DATES: August 15, 1997.

FOR FURTHER INFORMATION CONTACT: LTJG B.V. Howard, Coast Guard Group, St. Petersburg, FL at (813) 824-7533.

SUPPLEMENTARY INFORMATION:

Regulatory History

In accordance with 5 U.S.C. 553, the final rule will be made effective in less than 30 days from the date of publication in the **Federal Register**. Following normal rulemaking procedures would be impracticable and contrary to the public interest. A notice of proposed rulemaking was published on 16 July 1997 (62 FR 38042) with a twenty day comment period. The final rule will be made effective in less than thirty days in order to hold the event. No comments were received during the comment period.

Discussion of Regulations

The regulations are needed to provide for the safety of life during the Hurricane Offshore Classic. These regulations are intended to promote safe navigation on the waters off St. Petersburg during the races by controlling the traffic entering, exiting,

and traveling within these waters. The anticipated concentration of spectator and participant vessels associated with the Hurricane Offshore Classic poses a safety concern, which is addressed in these special local regulations. No anchoring will be permitted west of turns 1 and 4 nor west of turns 2 and 3, from 10 a.m. to 6 p.m. EDT.

Approximately 300 spectator craft will be permitted near the race area, but will be required to stay clear of the race lanes. The proposed regulations would also permit anchoring for spectators north of the northern straightaway and south of the southern straightaway, but only in the designated spectator area defined in 2.(b)(2) below.

All vessel traffic, not involved in the Hurricane Offshore Classic, entering or exiting the Vinoy Basin between 10 a.m. and 6 p.m. EDT must transit around the racecourse, taking action to avoid a close-quarters situation until finally past and clear of the racecourse. All vessel traffic, not involved with the Hurricane Offshore Classic, transiting the area off Coffeepot Bayou, The Pier, and Bayboro Harbor should exercise extra caution and take action to avoid a close-quarters situation until finally past and clear of the racecourse.

Regulatory Evaluation

This rule is not a significant regulatory action under Section 3(f) of the Executive Order 12866 and does not require an assessment of the potential costs and benefits under Section 6(a)(3) of that Order. It has been exempted from review 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 proposed rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. This regulation will last for approximately 8 hours each day for two days.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard considers whether this rulemaking will have a significant economic impact on a substantial number of small entities. "Small entities" include small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

Therefore, the Coast Guard certifies under 5 U.S.C. 605 (b) that this rule will

not have a significant economic impact on a substantial number of small entities as the regulation will be in effect for approximately eight hours in a limited area only two days each year.

Collection of Information

These regulations contain no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that the rulemaking does not have sufficient Federalism implications to warrant the preparation of a Federalism Assessment.

Environmental Assessment

The Coast Guard has considered the environmental impact of this proposal consistent with Section 2.B.2. of Commandant Instruction M16475.1B. In accordance with that section, this action has been environmentally assessed (EA completed), and the Coast Guard has concluded that it will not significantly affect the quality of the human environment. An Environmental Assessment and a Finding of No Significant Impact have been prepared and are available in the docket for inspection and copying.

List of Subjects in 33 CFR Part 100

Marine Safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

Final Regulations

In consideration of the foregoing, the Coast Guard amends Part 100 of Title 33, Code of Federal Regulations, as follows:

1. The authority citation for Part 100 continues to read as follows:

PART 100—[AMENDED]

Authority: 33 U.S.C. 1233; 49 CFR 1.46, 33 CFR 100.35.

2. A new section 100.728 is added to read as follows:

§ 100.728 Special Local Regulations; Hurricane Offshore Classic, St. Petersburg, FL.

(a) *Regulated area.* The regulated area is formed by a line drawn from position 27°46.9'N, 082°37.45'W (onshore at North Shore Park) east southeast to position 27°46.39'N, 082°32.65'W; thence due south to position 27°44.67'N, 082°32.65'W; thence due west to position 27°44.67'N, 082°37.45'W (onshore just south of

Lassing Park). All coordinates referenced use Datum: NAD 83.

(b) *Special local regulations.* (1) Entry into the regulated area by other than event participants is prohibited unless authorized by the patrol commander designated by Coast Guard Group St. Petersburg, Florida.

(2) Spectator craft will be permitted near the race area, but will be required to stay clear of the race lanes. Anchoring for spectator craft is permitted north of the northern straightaway and south of the southern straightaway, but only in the designated spectator area between 27°46.62N, 082°37.00W to 27°46.80N, 082°34.72W and 27°46.52N, 082°37.00W to 27°46.70N, 082°34.72W for the northern area and 27°46.25N, 082°37.00W to 27°45.90N, 082°34.72W and 27°46.15N, 082°37.00W to 27°45.80N, 082°34.72W for the southern area. All coordinates referenced use Datum: NAD 83. No anchoring will be permitted west of turns 1 and 4 nor west of turns 2 and 3, from 10 a.m. to 6 p.m. EDT.

(3) All vessel traffic, not involved in the Hurricane Offshore Classic, entering or exiting the Vinoy Basin between 10 a.m. and 6 p.m. EDT must transit around the racecourse, taking action to avoid a close-quarters situation until finally past and clear of the racecourse. All vessel traffic, not involved with the Hurricane Offshore Classic, transiting the area off Coffeepot Bayou, The Pier, and Bayboro Harbor should exercise extra caution and take action to avoid a close-quarters situation until finally past and clear of the racecourse.

(4) Entry into the regulated area shall be in accordance with this section. Spectator vessels will at all times stay in the spectator areas defined in paragraph (b)(2) of this section.

(c) *Effective Dates:* This regulation is effective annually at 10 a.m. and terminates at 6 p.m. EDT on the third Saturday and Sunday of August.

Dated: August 7, 1997.

N.T. Saunders,

Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.

[FR Doc. 97-21809 Filed 8-13-97; 1:03 pm]

BILLING CODE 4910-14-M

POSTAL SERVICE

39 CFR Part 3

Board of Governors Bylaws

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: The Board of Governors of the United States Postal Service has

approved an amendment to its bylaws. The amendment describes how the cost of a development real estate project is determined for purposes of applying the bylaw requirement for Board approval of capital investment projects above \$10 million.

EFFECTIVE DATE: August 15, 1997.

FOR FURTHER INFORMATION CONTACT: Thomas J. Koerber, (202) 268-4800.

SUPPLEMENTARY INFORMATION: The Board of Governors of the Postal Service consists of nine Presidentially appointed Governors, and the Postmaster General and Deputy Postmaster General. 39 U.S.C. 202. The bylaws of the Board list certain matters reserved for action by the Board. 39 CFR 3.3. Among the matters reserved is the approval of each capital investment project in excess of a dollar amount specified by annual resolution of the Board each January, currently \$10 million. At its meeting on August 5, 1997, the Board approved an amendment to the bylaw to explain how to compute the cost of developmental real estate projects for purposes of determining whether the project is of sufficient magnitude to come before the Board for approval under this provision.

The amendment provides that the cost of developmental real estate projects is computed by combining three elements. These are the value of the assets contributed by the Postal Service, the cash contributed by the Postal Service, and any debt that would impact the Postal Service investment.

List of Subjects in 39 CFR Part 3

Administrative practice and procedure, Organization and functions (Government agencies), Postal Service.

Accordingly, 39 CFR Part 3 is amended as follows:

PART 3—[AMENDED]

1. The authority citation for Part 3 continues to read as follows:

Authority: 39 U.S.C. 202, 203, 205, 401 (2), (10), 402, 1003, 2802-2804, 3013; 5 U.S.C. 552b (g), (j); Inspector General Act, 5 U.S.C. app.

2. Section 3.3 is amended by adding new paragraph (e)(3) to read as follows:

§ 3.3 Matters reserved for decision by the Board.

* * * * *

(e) * * *

(3) The cost of a developmental real estate project shall be the sum of:

(i) The as-is value of the postal assets contributed to the project;

(ii) Cash contributed by the Postal Service; and

(iii) Debt that impacts the Postal Service's investment.

* * * * *

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. 97-21589 Filed 8-14-97; 8:45 am]

BILLING CODE 7710-12-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[AD-FRL-5875-8]

National Ambient Air Quality Standards for Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; extension of supplemental public comment period.

SUMMARY: EPA is announcing an extension of the supplemental comment period that was first announced on July 18, 1997 for the limited purpose of taking comment on certain laboratory and field test data and related reports associated with the development of the reference method (Appendix L of 40 CFR part 50) for measuring PM_{2.5} in the ambient air.

DATES: Written comments must be received on or before September 8, 1997.

ADDRESSES: Submit written comments (duplicate copies preferred) to: Office of Air and Radiation Docket and Information Center (6102), Attn: Docket No. A-95-54, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: John H. Haines, MD-15, Air Quality Strategies and Standards Division, Office of Air Quality Planning and Standards, Environmental Protection Agency, Research Triangle Park, NC 27711, telephone: (919) 541-5533, e-mail: haines.john@epamail.epa.gov or Neil H. Frank, MD-14, Emissions, Monitoring and Analysis Division, Office of Air Quality Planning and Standards, Environmental Protection Agency, Research Triangle Park, NC 27711, telephone: (919) 541-5560, e-mail: frank.neil@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: On July 18, 1997 (62 FR 38652), EPA published the final rule revising the national ambient air quality standards for particulate matter. In Unit VI.B. (Appendix L—New Reference Method for PM_{2.5}), EPA concluded that the proposed design and performance specifications for the reference sampler,

with modifications described in the final rule, will achieve the design objectives set forth in the proposal. Accordingly, EPA has adopted the sampler and other method requirements specified in the revised Appendix L as the reference method for measuring PM_{2.5} in the ambient air. As discussed in the preamble to the final rule, a series of field tests were performed using prototype samplers manufactured in accordance with the proposed design and performance specifications. The results of these field tests confirmed that the prototype samplers perform in accordance with design expectations. Operational experience gained through these field tests did, however, identify the need for minor modifications as discussed in the preamble to the final rule. As explained in that preamble, EPA made other modifications to the proposed design and performance specification in response to public comment. As part of this process, EPA performed laboratory tests to ensure that the modifications achieved the intended objective.

While the results of the field and laboratory tests were largely confirmatory in nature and did not indicate a need to alter the basic design and performance specifications, they did identify areas that needed further refinement. Given that these tests were performed, by necessity, during and after the close of the public comment period and because the results were not available for placement in the docket until late in the rulemaking process, the preamble to the final rule announced that a supplemental comment period would be held for the limited purpose of taking comments on these field and laboratory tests results. The July 18, 1997 action announcing the supplemental comment period (62 FR 38762), identified the following documents:

1. "Adaptation of the Low-Flowrate, PM₁₀, Dichotomous Sampler Inlet to Fine Particle Collection."
2. "Filter Temperature Specification Report."
3. "Flow Rate Specification Report."
4. "Laboratory and Field Evaluation of FRM Sampler Report."
5. "Prototype PM_{2.5} Federal Reference Method Field Studies Report."

The July 18, 1997 action emphasized that the supplemental comment period was for the limited purpose of taking comment on the documents specified in the July 18, 1997 action only. Comments on the reference method for PM_{2.5} that go beyond the scope of these specific documents would not be considered. The July 18, 1997 action indicated that upon close of the supplemental

comment period, EPA would consider the comments received and decide whether any further action is appropriate.

Since the supplemental comment period was announced, EPA has identified errors in the "Prototype PM_{2.5} Federal Reference Method Field Studies Report". As a result, EPA has prepared three correction pages and has entered them into Docket No. A-95-54 and they are available for inspection and copying at the Office of Air and Radiation Docket and Information Office at the address in **ADDRESSES** at the beginning of this document. Copies may also be obtained by contacting Neil H. Frank at the address in **FOR FURTHER INFORMATION CONTACT**. In order to provide opportunity for the public to review and comment on these corrected pages, and to permit additional time for interested parties that could not immediately obtain copies of the five documents, EPA is extending the supplemental comment period until September 8, 1997.

List of Subjects in 40 CFR Part 50

Environmental protection, Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

(Authority: Secs. 108 and 109, Clean Air Act, as amended (42 U.S.C. 7408, 7409)).

Dated: August 7, 1997.

Mary Nichols,

Assistant Administrator for Air and Radiation.

[FR Doc. 97-21697 Filed 8-14-97; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[TN-142-9727(a); FRL-5872-9]

Approval and Promulgation of Revisions to Tennessee SIP Chapter 1200-3-5 Visible Emissions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: On October 4, 1994, Tennessee submitted, through the Department of Environment and Conservation, a new chapter 1200-3-5 Visible Emissions to replace the existing chapter 1200-3-5 Visible Emissions in the Tennessee State Implementation Plan (SIP). These revisions include amendments and repeals of existing rules. EPA is approving these amendments and repeals as they conform to the requirements of the SIP

as set out in the Clean Air Act (CAA) as amended in 1990.

DATES: This final rule is effective October 14, 1997 unless adverse or critical comments are received by September 15, 1997. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: Written comments on this action should be addressed to Randy Terry at the Environmental Protection Agency, Region 4 Air Planning Branch, 61 Forsyth Street, Atlanta, Georgia 30303.

Copies of documents relative to this action are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day and reference file TN 142-01-9727. The Region 4 office may have additional background documents not available at the other locations.

Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

Environmental Protection Agency, Region 4 Air Planning Branch, 61 Forsyth Street, SW., Atlanta, Georgia 30303.

Department of Environment and Conservation, 9th Floor L & C Annex, 401 Church St, Nashville, TN 37243-1531.

FOR FURTHER INFORMATION CONTACT:

Randy Terry, Regulatory Planning Section, Air Planning Branch, Air, Pesticides & Toxics Management Division, Region 4 Environmental Protection Agency, 61 Forsyth Street SW., Atlanta, Georgia, 30303. The telephone number is (404) 562-9032.

SUPPLEMENTARY INFORMATION: On October 4, 1994, Tennessee submitted, through the Department of Environment and Conservation, revisions to the Tennessee SIP. Tennessee submitted a new chapter 1200-3-5 Visible Emissions to replace the existing chapter. This new chapter contains all of the changes made to the chapter. In this document, the specific changes to each regulation will be independently addressed.

Chapter 1200-3-5-.01 General Standard

This rule was amended to incorporate paragraphs (2) and (3) which require that all sources identified in chapter 1200-3-19 must comply with this rule. This rule also allows for an emission limit to be set that is more restrictive than that otherwise specified in this

chapter if there is mutual agreement between any air contaminant source and the Technical Secretary.

Chapter 1200-3-5-.02 Exceptions

This rule was amended to adopt language that allows for the Technical Secretary to conduct an Administrative Hearing in the event of a dispute between the owner or operator of an air contaminant source and the Tennessee Air Pollution Control Division.

Chapter 1200-3-5-.03 Methods of Evaluation and Recording

This rule was amended to set forth the provisions in which a determination of visible emissions can be made and specifies that a certified evaluator (evaluator must be certified by criteria approved by the board) must make the determination. This rule specifies that obscuration of vision caused by water droplets shall not be considered a violation of this rule and that all new and/or modified sources on or after July 7, 1992, subject to the provisions in this chapter shall utilize six-minute averaging. Visible emissions determinations for roads and parking lots shall utilize two-minute averaging.

Chapter 1200-3-5-.04 Exemption

This rule was amended to clarify the restrictions on when the exemption to visible emissions can be applied. The rule allows for exemptions from fuel-burning equipment used exclusively to provide space heating in a building containing not more than two (2) dwelling units. In addition this rule also exempts all sources that have an applicable visible emissions standard under chapter 1200-3-16.

Chapter 1200-3-5-.05 Standard for Certain Existing Sources

This rule was adopted to set the emission standards that certain sources must meet. This rule applies to all sources meeting the conditions in paragraphs (2) and (3) of this rule and for which a certificate of validation has been issued by the Technical Secretary indicating that the conditions in paragraph (2) are met. The selected sources must have no visible emissions in excess of forty percent opacity for an aggregate of more than five minutes in any one hour or more than twenty minutes in any twenty four hour period.

The Technical Secretary must issue a certificate of validation if the owner or operator of the air contaminant source demonstrates to the satisfaction of the Technical Secretary that certain conditions are met. The conditions include but are not limited to the air contaminant source being subject to the

rules contained in either Chapter 1200-3-6 or Chapter 1200-3-7 and meeting the appropriate emission standard contained in those chapters.

Chapter 1200-3-5-.07 Certain Wood Fired Fuel Burning Equipment

This rule was repealed.

Chapter 1200-3-5-.06 Wood-Fired Fuel Burning Equipment, Chapter 1200-3-5-.08 Titanium Dioxide (TiO₂) Manufacturing, 1200-3-5.10 Choice of Visible Emission Standards for Certain Fuel Burning Equipment and 1200-3-5.11 Soda Recovery Boilers

These rules were not revised.

Chapter 1200-3-5-.09 Kraft Mill Recovery Furnaces

This rule was amended to include a section that specifies that the proper procedure for a source to obtain the applicable opacity de minimus level is to monitor the opacity emissions as described in Rule 1200-3-5-.02.

Chapter 1200-3-5-.12 Coke Battery Underfire (Combustion) Stacks

This rule was added to set provisions that would allow an owner or operator of a coke battery underfire stack to elect within 30 days of notification of violation to conduct particulate emissions testing in accordance with the provisions of this chapter. The particulate emissions testing would be done to demonstrate compliance with the applicable particulate mass limitation within 45 days of the election. In the event that this testing demonstrates compliance with the mass emission limitation and visible emissions are in excess of the opacity limitation during this testing, the opacity observed during such testing shall become the alternate opacity limitation for that emission point. This rule also sets forth the appropriate methods to be used to determine an alternate opacity limitation.

Final Action

EPA is approving Tennessee's revisions submitted on October 6, 1994, for incorporation into the Tennessee SIP. The EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in a separate document in this **Federal Register** publication, the EPA is proposing to approve the SIP revision should adverse or critical comments be filed. This action will be effective October 14, 1997 unless, by September 15, 1997, adverse or critical comments are received.

If the EPA receives such comments, this action will be withdrawn before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will be addressed in a subsequent final rule based on this action serving as a proposed rule. The EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. If no such comments are received, the public is advised that this action will be effective October 14, 1997.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any SIP. Each request for revision to the SIP shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from E.O. 12866 review.

B. Regulatory Flexibility Act

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 any small entities affected. Moreover, due to the nature of the Federal-State relationship under the CAA, preparation of a 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. EPA*, 427 U.S. 246, 255-66 (1976); 42 U.S.C. 7410(a)(2) and 7410(k)(3).

C. 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 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 approval 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 requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

D. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

E. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 14, 1997. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations,

Reporting and recordkeeping requirements.

Dated: July 9, 1997.

Michael V. Peyton,

Acting Regional Administrator.

Part 52 of chapter I, title 40, Code of Federal Regulations, is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42.U.S.C. 7401-7671q.

Subpart RR—Tennessee

2. Section 52.2220 is amended by adding paragraph (c)(157) to read as follows:

§ 52.2220 Identification of plan.

* * * * *

(c) * * *

(157) The visible emission chapter revisions to the Tennessee SIP which were submitted on October 6, 1994.

(i) Incorporation by reference.

(A) Chapter 1200-3-5 Visible Emissions effective on June 7, 1992.

(ii) Other material. None.

* * * * *

[FR Doc. 97-21699 Filed 8-14-97; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 128-0043; FRL-5875-9]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, San Joaquin Valley Unified Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action on revisions to the California State Implementation Plan. The revisions concern negative declarations from the San Joaquin Valley Unified Air Pollution Control District (SJVUAPCD) for five source categories that emit oxides of nitrogen (NO_x): Nitric and Adipic Acid Manufacturing Plants, Cement Manufacturing Plants, Asphalt Batch Plants, Iron and Steel Manufacturing Plants, and Driers. The SJVUAPCD has certified that these source categories are not present in the District and this information is being added to the federally approved State Implementation Plan. The intended

effect of approving these negative declarations is to meet the requirements of the Clean Air Act, as amended in 1990 (CAA or the Act). Thus, EPA is finalizing the approval of these revisions into the California SIP under provisions of the CAA regarding EPA action on SIP submittals, SIPs for national primary and secondary ambient air quality standards and plan requirements for nonattainment areas.

DATES: This action is effective on October 14, 1997 unless adverse or critical comments are received by September 15, 1997. If the effective date is delayed, a timely notice will be published in the **Federal Register**.

ADDRESSES: Comments must be submitted to Julie Rose at the Region IX office listed below. Copies of the submitted negative declarations are available for public inspection at EPA's Region IX office and also at the following locations during normal business hours.

Rulemaking Office (AIR-4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105

Air Docket (6102), U.S. Environmental Protection Agency, 401 "M" Street, S.W., Washington, D.C. 20460
California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 "L" Street, Sacramento, CA 92123-1095
San Joaquin Valley Unified Air Pollution Control District, 1999 Tuolumne Street, Fresno, CA 93721

FOR FURTHER INFORMATION CONTACT: Julie A. Rose, Rulemaking Office (AIR-4), Air Division, U.S. Environmental Protection Agency, 75 Hawthorne Street, San Francisco, CA 94105, Telephone: (415) 744-1184.

SUPPLEMENTARY INFORMATION:

I. Applicability

The revisions being approved as additional information for the California SIP include five negative declarations from the SJVUAPCD regarding the following source categories: (1) Nitric and Adipic Acid Manufacturing Plants, (2) Cement Manufacturing Plants, (3) Asphalt Batch Plants, (4) Iron and Steel Manufacturing Plants, and (5) Driers. These negative declarations were submitted by the California Air Resources Board (CARB) to EPA on October 17, 1994.

II. Background

On November 15, 1990, the Clean Air Act Amendments of 1990 (CAA) were enacted. Public Law 101-549, 104 Stat.

2399, codified at 42 U.S.C. 7401–7671q. The air quality planning requirements for the reduction of NO_x emissions through reasonably available control technology (RACT) are set out in section 182(f) of the CAA. On November 25, 1992, EPA published a proposed rulemaking entitled “State Implementation Plans; Nitrogen Oxides Supplement to the General Preamble; Clean Air Act Amendments of 1990 Implementation of Title I; Proposed Rule,” (the NO_x Supplement) which describes the requirements of section 182(f). The NO_x Supplement should be referred to for further information on the NO_x requirements and is incorporated into this document by reference. Section 182(f) of the Clean Air Act requires states to apply the same requirements to major stationary sources of NO_x (“major” as defined in section 302 and section 182 (c), (d), and (e)) as are applied to major stationary sources of volatile organic compounds (VOCs), in moderate or above ozone nonattainment areas. The San Joaquin Valley Air Basin (SJVAB) is classified as a serious nonattainment area for ozone.¹ The SJVAB area is subject to the RACT requirements of section 182(b)(2), cited above.

Section 182(b)(2) requires submittal of RACT rules for major stationary sources of VOC emissions (not covered by a pre-enactment control technique guidelines (CTG) document or a post-enactment CTG document) by November 15, 1992. There were no NO_x CTGs issued before enactment and EPA has not issued a CTG document for any NO_x category since enactment of the CAA. EPA has issued guidance documents in the form of Alternative Control Techniques for nine NO_x source categories: (1) Nitric and Adipic Acid Manufacturing Plants, (2) Stationary Combustion Gas Turbines, (3) Process Heaters, (4) Stationary Internal Combustion Engines, (5) Utility Boilers, (6) Cement Manufacturing, (7) Glass Manufacturing, (8) Iron and Steel Plants, and (9) Industrial, Commercial, and Institutional Boilers.

The five negative declarations were adopted on September 14, 1994 and submitted by the State of California on October 17, 1994. The submitted negative declarations were found to be complete on December 1, 1994 pursuant to EPA’s completeness criteria that are set forth in 40 CFR part 51 Appendix V.²

¹ The San Joaquin Valley Air Basin retained its designation of nonattainment and was classified by operation of law pursuant to sections 107(d) and 181(a) upon the date of enactment of the CAA. See 55 FR 56694 (November 6, 1991).

² EPA adopted the completeness criteria on February 16, 1990 (55 FR 5830) and, pursuant to

These negative declarations are being finalized for approval into the SIP as additional information.

This document addresses EPA’s direct final action for the SJVUAPCD negative declarations for: (1) Nitric and Adipic Acid Manufacturing Plants, (2) Cement Manufacturing Plants, (3) Asphalt Batch Plants, and (4) Iron and Steel Manufacturing Plants, and (5) Driers. The submitted negative declarations certify that there are no NO_x sources in these source categories located inside SJVUAPCD. Therefore, the determination being evaluated is that there is no need to have RACT rules in the SIP for these source categories at this time.

III. EPA Evaluation and Action

In determining the approvability of a negative declaration, EPA must evaluate the declarations for consistency with the requirements of the CAA and EPA regulations, as found in section 110 of the CAA and 40 CFR part 51 (Requirements for Preparation, Adoption, and Submittal of Implementation Plans).

In a Resolution dated September 14, 1994, the SJVUAPCD Board affirmed that the SJVUAPCD does not have any major stationary sources in these source categories located within the federal ozone nonattainment planning area.

EPA has evaluated these negative declarations and has determined that they are consistent with the CAA, EPA regulations, and EPA policy. SJVUAPCD’s negative declarations for Nitric and Adipic Acid Manufacturing Plants, Cement Manufacturing Plants, Asphalt Batch Plants, Iron and Steel Manufacturing Plants, and Driers are being approved under section 110(k)(3) of the CAA as meeting the requirements of section 110(a) and Part D.

EPA is publishing this document without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in a separate document in this **Federal Register** publication, the EPA is proposing to approve the SIP revision should adverse or critical comments be filed. This action will be effective October 14, 1997, unless, by September 15, 1997, adverse or critical comments are received.

If the EPA receives such comments, this action will be withdrawn before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be

section 110(k)(1)(A) of the CAA, revised the criteria on August 26, 1991 (56 FR 42216).

addressed in a subsequent final rule based on this action serving as a proposed rule. The EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. If no such comments are received, the public is advised that this action will be effective October 14, 1997.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future 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.

IV. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from E.O. 12866 review.

B. Regulatory Flexibility Act

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 Clean Air Act 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, the Administrator certifies that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the CAA, preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co. v. U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

C. 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 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 approval 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.

D. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a "major" rule as defined by 5 U.S.C. 804(2).

E. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 14, 1997. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Intergovernmental relations, Nitrogen dioxide, Reporting and recordkeeping

requirements, Volatile organic compounds.

Dated: August 1, 1997.

Felicia Marcus,

Regional Administrator.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401-7671q.

Subpart F—California

2. Section 52.222 is being amended by adding paragraph (b)(2) to read as follows:

§ 52.222 Negative declarations.

* * * * *

(b) * * *

(2) San Joaquin Valley Unified Air Pollution Control District.

(i) Nitric and Adipic Acid Manufacturing Plants, Cement Manufacturing Plants, Asphalt Batch Plants, Iron and Steel Manufacturing Plants, and Driers were submitted on October 17, 1994 and adopted on September 14, 1994.

* * * * *

[FR Doc. 97-21694 Filed 8-14-97; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MO-028-1028; FRL-5875-7]

Approval and Promulgation of Implementation Plans; State of Missouri

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final notice of the Herculaneum, Missouri, nonattainment area's failure to attain the National Ambient Air Quality Standard (NAAQS) for lead.

SUMMARY: Pursuant to the Clean Air Act (CAA or the Act), the EPA has notified the state of Missouri that the Doe Run-Herculaneum nonattainment area failed to attain the NAAQS for lead (Pb) by June 30, 1995, as required under the provisions of the Act and the Missouri State Implementation Plan (SIP). This notification is based on the EPA's review of monitored air quality data for compliance with the NAAQS for lead. This notice is issued pursuant to the EPA's obligations under sections 179(c)

(1) and (2) of the CAA, which require the EPA to make a determination of an area's attainment status following an applicable attainment date, and publish a notice in the **Federal Register** indicating that such a determination has been made. Pursuant to section 179(d)(1) of the CAA, Missouri is required to submit a SIP revision, meeting the applicable provisions of the Act within one year of today's finding.

DATES: This action is effective on September 15, 1997.

ADDRESSES: Copies of the documents relevant to this action are available for public inspection during normal business hours at the: Environmental Protection Agency, Air Planning and Development Branch, 726 Minnesota Avenue, Kansas City, Kansas 66101.

FOR FURTHER INFORMATION CONTACT: Royan W. Teter at (913) 551-7609.

SUPPLEMENTARY INFORMATION:

I. Background

The EPA designated the area in the vicinity of the Doe Run Company's primary lead smelter in Herculaneum, Missouri, nonattainment with respect to the NAAQS for lead on November 6, 1991 (56 FR 56694). This designation became effective on January 6, 1992. Missouri initially submitted a SIP revision addressing the nonattainment designation in July 1993. Supplements were submitted in March and November 1994. The EPA approved Missouri's revised SIP on May 5, 1995 (60 FR 22274), establishing June 30, 1995, as the date by which the area was to have attained the NAAQS for lead. Ambient air monitoring data, as shown below, indicate that violations of the lead NAAQS have continued to occur in each calendar quarter subsequent to the attainment date. On March 5, 1997, the EPA published a proposed notice of failure to attain the NAAQS for the Herculaneum, Missouri, nonattainment area (62 FR 10001). The proposed notice detailed the responsibilities of the EPA and the state of Missouri under the CAA and provided the public with an opportunity to comment on the Agency's determination that the Herculaneum area has failed to attain the standard.

Lead Ambient Air Quality Data—Vicinity Of The DOE Run Primary Smelter

Calendar Quarterly Values

(Micrograms of lead per cubic meter of air ($\mu\text{g}/\text{m}^3$))

HI—VOL MONITOR LOCATIONS

Date	Dunklin 29-099-0014	Dunklin 29-099-0005	Golf Course 29-099-0008	North 29-099-0009	Ursaline 29-099-0010	Rutz 29-099-0011	Div. Manager 29-099-0013	Broad Street 29-099-0015
	S	H	H	H	H	H	H	H
1995:								
3rd	1.4	1.2	0.3	0.3	0.2	1.0	1.2	4.1
4th	1.9	1.7	0.4	0.8	0.1	1.6	1.3	6.3
1996:								
1st	2.3	1.9	0.3	0.4	0.1	1.4	.8	2.3
2nd	1.6	1.2	0.5	0.1	0.2	2.4	0.8	5.7
3rd	0.8	0.6	0.1	0.2	0.3	0.7	0.5	4.0
4th	1.7	1.8	0.1	0.5	0.3	1.4	0.9	1.6

Notes:

¹(S) = State monitor, (H) = Asarco monitor.

²Italicized Quarterly Air Quality Values exceed the National Ambient Air Quality Standard (NAAQS) for lead; the NAAQS for lead is 1.5 µg/m³ and is the arithmetic mean of a series of daily (24-hour) values from hi-vol monitors measuring particulate matter, within a 3-month (calendar quarter) period.

II. Response To Comments

The EPA received 334 letters regarding the Doe Run Company and its Herculaneum, Missouri, operations. Those submitting comments included 25 businesses, 108 members of The Doe Run Company's mining and milling division, and 201 other Doe Run employees. None of the comments pertained specifically to the EPA's determination that the Herculaneum nonattainment area failed to attain the NAAQS for lead by the prescribed date, as discussed in the March 5, 1997, proposed action. Nevertheless, the EPA believes it is appropriate to outline the major themes discussed by those who submitted comments and provide a response.

Comments: All commentors expressed support for the Doe Run Company and encouraged the EPA to work cooperatively with the Company to address the air quality issues within the nonattainment area. Three distinct

rationales were presented. One group of commentors cited the Company's success in reducing toxic chemical releases to the environment while participating in the EPA's 33/50 Program. Another group of commentors cited recent expenditures totaling \$900,000 as evidence of the Company's desire to fulfill the corporate philosophy to "Make it better tomorrow than it is today." A third group acknowledged Doe Run as an important contributor to the economies of the state and the nation, and expressed concern over any actions that the EPA might take that could place the company at an economic disadvantage and jeopardize the company's survival.

Response: The EPA will work cooperatively with the Doe Run Company and the Missouri Department of Natural Resources to develop a SIP that meets the requirements of the CAA. The EPA is an active participant in discussions related to the development

of an appropriate emissions control strategy. Recent discussions have yielded positive results. Some data collection activities are already underway and a framework has been developed for future activities. These activities will facilitate a better understanding of the sources of emissions that are contributing to violations of the NAAQS.

The Doe Run Company's success in the 33/50 Program and its latest efforts to reduce lead emissions from the Herculaneum smelter are commendable actions; however, ambient lead concentrations in the vicinity of the smelter remain above the levels which are protective of public health and welfare. As such, the EPA is mandated by the CAA to publish a notice in the **Federal Register**, indicating the area's failure to attain the standard. The Act then requires that within one year, Missouri revise its SIP to address the violations of the air quality standard.

One group of commentors expressed concerns that the EPA's actions may jeopardize the economic future of the Doe Run Company. While cost will be a factor in determining the final control plan, it is important to understand that the EPA's determination regarding the Herculaneum area's failure to attain the NAAQS for lead involves only a factual finding based on air quality measurements. This determination does not impose any specific requirements or limitations on the Doe Run Company. Any such requirements will be specified in Missouri's SIP.

III. Final action

Today's action finalizes the EPA's determination that the Herculaneum, Missouri, nonattainment area did not attain the NAAQS for lead by June 30, 1990, as prescribed by CAA and Missouri's SIP. This action invokes section 179(d) of the CAA which, under the circumstances, requires Missouri to submit a SIP revision meeting the implementation and nonattainment plan provisions of the Act, and any additional measures which may be reasonably prescribed in order to bring the area into attainment with the NAAQS. This SIP revision must be submitted within one year of today's action.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any SIP. Each request for revision to the SIP shall be considered separately in light of specific technical, economic, and environmental factors, and in relation to relevant statutory and regulatory requirements.

IV. Administrative Requirements

A. Executive Order (EO) 12866

Under E.O. 12866, 58 FR 51735 (October 4, 1993), the EPA is required to determine whether regulatory actions are significant and therefore should be subject to the Office of Management and Budget review, economic analysis, and the requirements of the Executive Order. The Executive Order 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), 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 Agency has determined that today's action does not result in any of the effects identified in 3(f). Under sections 179(c) and 179(c)(2), a determination that an area has failed to attain the NAAQS for lead and the call for revision of the relevant SIP 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.

B. Regulatory Flexibility

Under the Regulatory Flexibility Act, 5 U.S.C. 600 et seq., the 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, the EPA may

certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

As previously discussed, a determination that an area has failed to attain the lead NAAQS and its associated SIP call, do not in-and-of-themselves create any new requirements. Therefore, I certify that today's final action does not have a significant impact on small entities.

C. 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, the EPA must assess whether various actions undertaken in association with proposed or final regulations 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.

The EPA believes, as discussed above, that its determination that the Herculaneum, Missouri, area has failed to attain the NAAQS for lead is a factual determination based upon air quality considerations and must occur by operation of law and, hence, does not impose any Federal intergovernmental mandate, as defined in section 101 of the Unfunded Mandates Act.

D. Small Business Regulatory Fairness Act (SBREFA)

Under 5 U.S.C. 801(a)(1)(A) as added by the Small Business Regulatory

Enforcement Fairness Act of 1996, the EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

E. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 14, 1997. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review, nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401–7671q.

Dated: August 4, 1997.

Michael J. Sanderson,

Acting Regional Administrator.

[FR Doc. 97–21702 Filed 8–14–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300530; FRL–5738–3]

RIN 2070–AB78

Replicase Protein of Potato Leaf Roll Virus and the Genetic Material Necessary for Its production; Exemption from the requirement of a tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of the biological pesticide Replicase Proteins of Potato Leaf Roll Virus and the genetic material

necessary for its production in or on all raw agricultural commodities. Monsanto Company submitted a petition to EPA under the Federal Food, Drug and Cosmetic Act as amended by the Food Quality Protection Act of 1996 requesting the tolerance exemption.

This regulation eliminates the need to establish a maximum permissible level for residues of Replicase Proteins of Potato Leaf Roll Virus and the genetic material necessary for its production.

DATES: This regulation is effective August 15, 1997. Objections and requests for hearings must be received by EPA on or before October 14, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300530], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300530], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP–300530]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Linda Hollis, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7501W),

Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail: Rm. 5th fl., CS#1 2800 Crystal Drive, Arlington, VA 22202, (703) 308–8733, e-mail: hollis.linda@epamail.epa.gov

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 25, 1997 (62 FR 34283–34286)(FRL–5723–2), EPA issued a notice pursuant to section 408(d), of the Federal Food Drug & Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), announcing the filing of a pesticide tolerance petition by Monsanto Corporation, St. Louis, MO. The notice contained a summary of the petition prepared by the petitioner and this summary contained conclusions and arguments to support its conclusion that the petition complied with the Food Quality Protection Act (FQPA) of 1996. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the biological pest control agent Replicase Protein of Potato Leaf Roll Virus and the genetic material necessary for its production in or on all raw agricultural commodities.

There were no comments or requests for referral to an advisory committee received in response to the notice of filing.

The data submitted in the petition and other material have been evaluated. The toxicology data requirements in support of this exemption from the requirement of a tolerance were satisfied via data waivers from the open scientific literature.

I. Risk Assessment and Statutory Findings

New section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(c)(2)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(c)(2)(B) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical

residue***." EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

II. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Additionally, section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." All available information indicates that viral coat proteins in food have no human toxicity and EPA is not aware of any other substances within or outside of the food supply that might have a common mechanism of human toxicity with residues of viral coat proteins produced in plants as part of a plant-pesticide.

Data waivers were requested for acute toxicity, genotoxicity, reproductive and developmental toxicity, subchronic toxicity and chronic toxicity data. The data waivers were accepted based on the long history of mammalian consumption of the entire plant virus particle in foods, without causing any deleterious human health effects [See OPP-300367A; FRL-5716-6]. Virus-infected plants currently are and have always been a part of both the human and domestic animal food supply and there have been no findings which indicate that plant viruses are toxic to humans and other vertebrates. Further, plant viruses are unable to replicate in mammals or other vertebrates, thereby eliminating the possibility of human infection. More importantly, however, this tolerance exemption will apply to that portion of the viral genome coding for the whole replicase protein and any subcomponent of the replicase protein expressed in the plant. This component alone is incapable of forming infectious particles.

The genetic material necessary for the production of the plant-pesticides active

and inert ingredients are the nucleic acids (DNA) which comprise (1) genetic material encoding these viral coat proteins and their regulatory regions. Regulatory regions are the genetic material that control the expression of the genetic material encoding the proteins, such as promoters, terminators, and enhancers. DNA is common to all forms of plant and animal life and the Agency knows of no instance where these nucleic acids have been associated with toxic effects related to their consumption as a component of food. These ubiquitous nucleic acids as they appear in the subject plant-pesticide's inert ingredient have been adequately characterized by the applicant and supports EPA's conclusion that no mammalian toxicity is anticipated from dietary exposure to the genetic material necessary for the production of the replicase protein of Potato Leaf Roll Virus and inert plant pesticidal ingredients.

III. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from groundwater or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. *Dietary exposure*—a. *Food*. The use of viral coat protein mediated resistance will not result in any new dietary exposure to plant viruses. Entire infectious particles of Potato Leaf Roll Virus, including the replicase protein component, are found in the fruit, leaves and stems of most plants. Viruses are ubiquitous in the agricultural environment at levels higher than will be present in transgenic plants. Virus infected food plants have historically been a part of the human and domestic animal food supply with no observed adverse effects to human health and infants and children upon consumption. Therefore, the lack of toxicity associated with plant viruses and the history of contamination of the food supply by replicase proteins provides a scientific rationale for exempting from the requirement of a tolerance transgenic plants expressing replicase proteins and leads the Agency to conclude that the use of Replicase Protein of Potato Leaf Roll Virus and the genetic material necessary for its production will not pose a dietary risk of concern under normal conditions. Moreover, there is no evidence which indicates that adverse effects due to aggregate

exposure of replicase proteins (with substances outside the food supply) through dietary, non-food oral, dermal and inhalation occurs. This conclusion is supported by the EPA's Scientific Advisory Panel's discussion regarding the Agency's Regulatory approach for plant pesticides which concluded:

i. The levels of virus in the agricultural environment are much higher than those levels present in transgenic plants.

ii. The existing contamination of the current food supply provides a scientific rationale for exempting from the requirement of a tolerance transgenic plants which express replicase proteins.

b. *Drinking water exposure*. Potential non-occupational exposures in drinking water is negligible. Replicase proteins produced in plants as part of a plant-pesticide are an integral part of the living tissue of the plant. As such, these components are subject to degradation and decay, a process which occurs fairly rapidly. Replicase proteins produced in plants as part of a plant-pesticide do not persist in the environment or bioaccumulate. The rapid turnover of these substances in the environment limits their ability to present anything other than a very negligible exposure in drinking water drawn from either surface or groundwater sources.

2. *Other non-occupational exposure*. Other non-occupational exposure of engineered coat proteins via residential and indoor uses, e.g., uses around homes, parks, recreation areas, athletic fields and golf courses, will be minimal to non-existent as the coat protein is expressed only within the plant tissues.

a. *Dermal exposure*. Due to the nature of replicase proteins produced in plants as part of a plant-pesticide, exposure through any route (i.e., dermal, respiratory) other than dietary is unlikely to occur. Physical contact with the plant or raw agricultural food from the plant may present some limited opportunity for dermal exposure. However, on a per person basis, the potential amounts involved in this exposure is negligible in comparison to exposure through the dietary route. Additionally, replicase proteins produced in plants as part of a plant-pesticide are unlikely to cross the barrier provided by the skin.

b. *Inhalation exposure*. The occurrence of respiratory exposure of replicase proteins produced in plants as part of a plant-pesticide is negligible in comparison to potential exposure through the dietary route. In some cases, replicase proteins may be present in pollen, thus affording exposure to those individuals in areas exposed to wind-blown pollen. However, it is unlikely

that exposure to the pollen is equivalent to exposure to replicase proteins produced in plants as part of a plant-pesticide. Replicase proteins, when present in pollen, will likely be integrated into the tissue of pollen grain and are unlikely to cross the barrier provided by the mucous membrane of the respiratory tract and thus are not additive to dietary exposure. Moreover, exposure through inhalation via wind-blown pollen occurs to the whole virus particle and there is no evidence which suggests that exposure to whole plant viruses by wind-blown pollen results in any adverse effects. Therefore, it is unlikely that exposure to pollen that may contain replicase proteins produced in plants as part of a plant-pesticide would result in adverse effects.

IV. Safety Factors

Rather than relying on available animal experimentation data to support a tolerance exemption for viral coat proteins, EPA relied on the long history of safe human consumption of food containing plant viruses as the appropriate information base for this tolerance exemption. Because the EPA did not rely on animal data, determination of appropriate safety factors to be used in a human risk assessment was not considered.

V. Infants and Children

Consistent with section 408(b)(2)(C) of the FFDCA, EPA has assessed the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. Based on all available information, the Agency concludes that replicase proteins produced in plants as part of a plant-pesticide are ubiquitous in foods, including those foods consumed by infants and children. Moreover, there is no reason to believe that plant replicase proteins are likely to occur in different amounts in foods, consumed by children and infants. Children are exposed as part of a normal diet to replicase proteins and there is no evidence which indicates that replicase proteins would have a different effect on children than on adults. Further, there is no evidence which suggests that such exposure to either adults or infants and children leads to any harm.

VI. Other Considerations

1. *Endocrine disrupters.* The Agency has no information to suggest that

Replicase Proteins of Potato Leaf Roll Virus and the genetic material necessary for its production will have an effect on the immune and endocrine systems. The Agency is not requiring information on the endocrine effects of this biological pesticide at this time; Congress has allowed 3 years after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects.

2. *Analytical method.* The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation; therefore, the agency has concluded that an analytical method is not required for enforcement purposes for Replicase Protein of Potato Leaf Roll Virus and the genetic material necessary for its production.

VII. Determination of Safety for U.S. Population, Infants and Children

For the U.S. population, including infants and children, Replicase Protein of Potato Leaf Roll Virus and the genetic material necessary for its production has no known adverse effects. Extensive use and experience show the safety of foods containing viral coat proteins. There has been no evidence in the many years of human experience with the growing and consumption of food from plants containing viral coat proteins which indicates that adverse effects due to aggregate exposure through the dietary, non-food oral, dermal and inhalation routes occur. Therefore, EPA concludes that there is reasonable certainty that no harm will result to the U.S. population from aggregate exposure to residues of replicase proteins produced in plants as part of a plant-pesticide including all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because, as discussed above, no toxicity to mammals has been observed for replicase protein of Potato Leaf Roll Virus and the genetic material necessary for its production. Thus, a tolerance for this Replicase Protein of Potato Leaf Roll Virus and the genetic material necessary for its production is not necessary to protect the public health. Therefore, 40 CFR part 180 is amended as set forth below.

VIII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA

currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by October 14, 1997, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the hearing clerk, at the address given under the "ADDRESSES" section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the hearing clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

IX. Public Docket

A record has been established for this rulemaking under docket control number [OPP-300530]. A public version of this record, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday,

excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above, is kept in paper form. Accordingly, in the event there are objections and hearing request, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record. The official rulemaking record is the paper record maintained at the Virginia address in "ADDRESSES" at the beginning of this document.

X. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In additions, since tolerance exemptions that are established on the

basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business.

XI. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This is not a major rule as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 7, 1997.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.1183 is added to subpart D to read as follows:

§ 180.1183 Replicase Protein of Potato Leaf Roll Virus and the genetic material necessary for its production; Exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biological plant pesticide Replicase Protein of Potato Leaf Roll Virus and the genetic material necessary for its production in or on all food commodities.

[FR Doc. 97-21691 Filed 8-14-97; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300531; FLR-5738-4]

RIN 2070-AB78

Coat Protein of Potato Virus Y and the Genetic Material Necessary for its Production; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of the biological pesticide Coat Proteins of Potato Virus Y and the genetic material necessary for its production in or on all raw agricultural commodities. Monsanto Company submitted a petition to EPA under the Federal Food, Drug and Cosmetic Act as amended by the Food Quality Protection Act of 1996 requesting the tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of Coat Proteins of Potato Virus Y and the genetic material necessary for its production.

DATES: This regulation is effective August 15, 1997. Objections and requests for hearings must be received by EPA on or before October 14, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP-300531], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300531], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of

electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP-300531]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Linda Hollis, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7501W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail: Rm. 5th fl., CS#1 2800 Crystal Drive, Arlington, VA 22202, (703) 308-8733, e-mail: hollis.linda@epamail.epa.gov

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 25, 1997 (62 FR 34281-34283)(FRL-5723-2), EPA issued a notice pursuant to section 408(d), of the Federal Food Drug & Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), announcing the filing of a pesticide tolerance petition by Monsanto Company, St. Louis, MO. The notice contained a summary of the petition prepared by the petitioner and this summary contained conclusions and arguments to support its conclusion that the petition complied with the Food Quality Protection Act (FQPA) of 1996. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the biological pest control agent Coat Protein of Potato Virus Y and the genetic material necessary for its production in or on all raw agricultural commodities.

There were no comments or requests for referral to an advisory committee received in response to the notice of filing.

The data submitted in the petition and other material have been evaluated. The toxicology data requirements in support of this exemption from the requirement of a tolerance were satisfied via data waivers from the open scientific literature.

I. Risk Assessment and Statutory Findings

New section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide

chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(c)(2)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(c)(2)(B) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue***." EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

II. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Additionally, section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." All available information indicates that viral coat proteins in food have no human toxicity and EPA is not aware of any other substances within or outside of the food supply that might have a common mechanism of human toxicity with residues of viral coat proteins produced in plants as part of a plant-pesticide.

Data waivers were requested for acute toxicity, genotoxicity, reproductive and developmental toxicity, subchronic toxicity and chronic toxicity data. The data waivers were accepted based on the long history of mammalian consumption of the entire plant virus particle in foods, without causing any

deleterious human health effects [See OPP-300367A; FRL-5716-6]. Virus-infected plants currently are and have always been a part of both the human and domestic animal food supply and there have been no findings which indicate that plant viruses are toxic to humans and other vertebrates. Further, plant viruses are unable to replicate in mammals or other vertebrates, thereby eliminating the possibility of human infection. More importantly, however, this tolerance exemption will apply to that portion of the viral genome coding for the whole coat protein and any subcomponent of the coat protein expressed in the plant. This component alone is incapable of forming infectious particles.

The genetic material necessary for the production of the plant-pesticides active and inert ingredients are the nucleic acids (DNA) which comprise (1) genetic material encoding these viral coat proteins and their regulatory regions. "Regulatory regions: are the genetic material that control the expression of the genetic material encoding the proteins, such as promoters, terminators, and enhancers. DNA is common to all forms of plant and animal life and the Agency knows of no instance where these nucleic acids have been associated with toxic effects related to their consumption as a component of food. These ubiquitous nucleic acids as they appear in the subject plant-pesticide's inert ingredient have been adequately characterized by the applicant and supports EPA's conclusion that no mammalian toxicity is anticipated from dietary exposure to the genetic material necessary for the production of the coat protein of Potato Virus Y and inert plant pesticidal ingredients.

III. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from groundwater or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. *Dietary exposure—a. Food.* The use of viral coat protein mediated resistance will not result in any new dietary exposure to plant viruses. Entire infectious particles of Potato Virus Y, including the coat protein component, are found in the fruit, leaves and stems of most plants. Viruses are ubiquitous in the agricultural environment at levels higher than will be present in transgenic

plants. Virus infected food plants have historically been a part of the human and domestic animal food supply with no observed adverse effects to human health and infants and children upon consumption. Therefore, the lack of toxicity associated with plant viruses and the history of contamination of the food supply by virus coat proteins provides a scientific rationale for exempting from the requirement of a tolerance transgenic plants expressing virus coat proteins and leads the Agency to conclude that the use of Coat Protein of Potato Virus Y and the genetic material necessary for its production will not pose a dietary risk of concern under normal conditions. Moreover, there is no evidence which indicates that adverse effects due to aggregate exposure of viral coat proteins (with substances outside the food supply) through dietary, non-food oral, dermal and inhalation occurs. This conclusion is supported by the EPA's Scientific Advisory Panel's discussion regarding the Agency's Regulatory approach for plant pesticides which concluded:

i. The levels of virus in the agricultural environment are much higher than those levels present in transgenic plants.

ii. The existing contamination of the current food supply provides a scientific rationale for exempting from the requirement of a tolerance transgenic plants which express viral coat proteins.

b. *Drinking water exposure.* Potential non-occupational exposures in drinking water is negligible. Viral coat proteins produced in plants as part of a plant-pesticide are an integral part of the living tissue of the plant. As such, these components are subject to degradation and decay, a process which occurs fairly rapidly. Viral coat proteins produced in plants as part of a plant-pesticide do not persist in the environment or bioaccumulate. The rapid turnover of these substances in the environment limits their ability to present anything other than a very negligible exposure in drinking water drawn from either surface or groundwater sources.

2. *Other non-occupational exposure.* Other non-occupational exposure of engineered coat proteins via residential and indoor uses, e.g., uses around homes, parks, recreation areas, athletic fields and golf courses, will be minimal to non-existent as the coat protein is expressed only within the plant tissues.

a. *Dermal exposure.* Due to the nature of viral coat proteins produced in plants as part of a plant-pesticide, exposure through any route (i.e., dermal, respiratory) other than dietary is unlikely to occur. Physical contact with the plant or raw agricultural food from

the plant may present some limited opportunity for dermal exposure. However, on a per person basis, the potential amounts involved in this exposure is negligible in comparison to exposure through the dietary route. Additionally, viral coat proteins produced in plants as part of a plant-pesticide are unlikely to cross the barrier provided by the skin.

b. *Inhalation exposure.* The occurrence of respiratory exposure of viral coat proteins produced in plants as part of a plant-pesticide is negligible in comparison to potential exposure through the dietary route. In some cases, viral coat proteins may be present in pollen, thus affording exposure to those individuals in areas exposed to wind-blown pollen. However, it is unlikely that exposure to the pollen is equivalent to exposure to viral coat proteins produced in plants as part of a plant-pesticide. Viral coat proteins, when present in pollen, will likely be integrated into the tissue of pollen grain and are unlikely to cross the barrier provided by the mucous membrane of the respiratory tract and thus are not additive to dietary exposure. Moreover, exposure through inhalation via wind-blown pollen occurs to the whole virus particle and there is no evidence which suggests that exposure to whole plant viruses by wind-blown pollen results in any adverse effects. Therefore, it is unlikely that exposure to pollen that may contain viral coat proteins produced in plants as part of a plant-pesticide would result in adverse effects.

IV. Safety Factors

Rather than relying on available animal experimentation data to support a tolerance exemption for viral coat proteins, EPA relied on the long history of safe human consumption of food containing plant viruses as the appropriate information base for this tolerance exemption. Because the EPA did not rely on animal data, determination of appropriate safety factors to be used in a human risk assessment was not considered.

V. Infants and Children

Consistent with section 408(b)(2)(C) of the FFDCA, EPA has assessed the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. Based on all available information, the Agency concludes that viral coat proteins

produced in plants as part of a plant-pesticide are ubiquitous in foods, including those foods consumed by infants and children. Moreover, there is no reason to believe that plant viral coat proteins are likely to occur in different amounts in foods, consumed by children and infants. Children are exposed as part of a normal diet to viral coat proteins and there is no evidence which indicates that viral coat proteins would have a different effect on children than on adults. Further, there is no evidence which suggests that such exposure to either adults or infants and children leads to any harm.

VI. Other Considerations

1. *Endocrine disrupters.* The Agency has no information to suggest that Coat Proteins of Potato Virus Y and the genetic material necessary for its production will have an effect on the immune and endocrine systems. The Agency is not requiring information on the endocrine effects of this biological pesticide at this time; Congress has allowed 3 years after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects.

2. *Analytical method.* The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation; therefore, the agency has concluded that an analytical method is not required for enforcement purposes for Coat Protein of Potato Virus Y and the genetic material necessary for its production.

VII. Determination of Safety for U.S. Population, Infants and Children

For the U.S. population, including infants and children, Potato Virus Y Coat Protein and the genetic material necessary for its production has no known adverse effects. Extensive use and experience show the safety of foods containing viral coat proteins. There has been no evidence in the many years of human experience with the growing and consumption of food from plants containing viral coat proteins which indicates that adverse effects due to aggregate exposure through the dietary, non-food oral, dermal and inhalation routes occur. Therefore, EPA concludes that there is reasonable certainty that no harm will result to the U.S. population from aggregate exposure to residues of viral coat proteins produced in plants as part of a plant-pesticide including all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because, as discussed above, no toxicity to mammals has been observed for coat

protein of Potato Virus Y and the genetic material necessary for its production. Thus, a tolerance for this Coat Protein of Potato Virus Y and the genetic material necessary for its production is not necessary to protect the public health. Therefore, 40 CFR part 180 is amended as set forth below.

VIII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by October 14, 1997, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the hearing clerk, at the address given under the "ADDRESSES" section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the hearing clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking

any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

IX. Public Docket

A record has been established for this rulemaking under docket control number [OPP-300531]. A public version of this record, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above, is kept in paper form. Accordingly, in the event there are objections and hearing request, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record. The official rulemaking record is the paper record maintained at the Virginia address in "ADDRESSES" at the beginning of this document.

X. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded

Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629), February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In additions, since tolerance exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business

XI. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This is not a major rule as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 7, 1997.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.1182 is added to subpart D to read as follows:

§ 180.1182 Coat Protein of Potato Virus Y and the genetic material necessary for its production; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biological plant pesticide Coat Protein of Potato Virus Y and the genetic material necessary for its production in or on all food commodities.

[FR Doc. 97-21690 Filed 8-14-97; 8:45 am]

BILLING CODE 6560-50-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 412, 413, and 414

[BPD-763-F]

RIN 0938-AG20

Medicare Program; End-Stage Renal Disease (ESRD) Payment Exception Requests and Organ Procurement Costs

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: These final regulations specify the criteria HCFA uses to determine if a facility that furnishes dialysis services to Medicare patients with end-stage renal disease (ESRD) qualifies for a higher payment under an exception to its prospectively determined payment rate and the procedures HCFA uses to evaluate ESRD payment exception requests. These regulations also revise the way HCFA computes acquisition costs for organs that are transplanted into Medicare beneficiaries.

EFFECTIVE DATE: September 15, 1997.

FOR FURTHER INFORMATION CONTACT: Michael Powell, (410) 786-4557.

SUPPLEMENTARY INFORMATION:

I. Background

Under sections 1881(b)(2) and (b)(7) of the Social Security Act (the Act), a facility that furnishes dialysis services to Medicare patients with ESRD is paid a prospectively determined rate for each dialysis treatment furnished. This rate is a composite that includes all costs associated with furnishing dialysis services except for the costs of physician services and certain laboratory tests and drugs that are billed separately. The composite rate may be adjusted periodically to reflect actual facility costs.

When a facility's costs are higher than the prospectively determined rate, we may, under certain conditions, grant the facility an exception to its composite rate and set a higher prospective rate. The facility must show, on the basis of projected cost and utilization trends, that it will have an allowable cost per treatment higher than its prospective payment rate and that the excess costs are attributable to one or more specific circumstances. These conditions are specified in existing regulations at 42 CFR 413.170 and are discussed in greater detail in Chapter 27 of the Medicare Provider Reimbursement Manual (PRM) (HCFA Pub. 15-1).

A facility may incur excess costs when it furnishes dialysis services to a patient population with a greater than average number of pediatric patients or patients with other medical conditions, such as those with heart disease or unstable medical conditions, who require special equipment, procedures, supplies, or staff trained in treating these patients. This is referred to as "atypical" service intensity (or patient mix). A facility may also incur increased costs when it is the only supplier of dialysis services in its geographical area and its patients are unable to obtain dialysis services elsewhere without considerable hardship (an isolated essential facility).

Increased training costs may also be associated with a facility's self-dialysis training program. A facility may train patients to perform self-dialysis with little or no professional assistance in the facility or at home. It may also train

other individuals to assist patients in performing self-dialysis or home dialysis. A facility that has training costs greater than its composite training rate may apply for an exception, but must prove that the costs are reasonable and allowable.

Typically, a patient undergoes dialysis three times a week. A facility may furnish a substantial number of treatments to patients who dialyze less frequently than three times a week. As a result, the facility typically has higher per treatment costs because the treatments involve increased labor or supplies. When this occurs, a facility may apply for an exception to the composite rate.

On several occasions, we have denied exception requests based on application of the criteria contained in the PRM, and the facilities have appealed the denials. Subsequently, some denials have been overturned by the Provider Reimbursement Review Board (PRRB) because the PRRB is not bound by the guidelines in the PRM. Therefore, we believe it is necessary to codify in regulations the specific requirements for determining exceptions.

II. Provisions of the Proposed Rule

On August 26, 1994, we published in the **Federal Register** (59 FR 44097) a proposed rule that specified the conditions (previously contained in the PRM) that a facility furnishing dialysis services to patients with ESRD must meet in order to qualify for a higher payment under an exception to the prospectively determined payment rate. The proposed rule also contained the criteria that we would use to evaluate whether the facility meets the conditions.

We also proposed to revise 42 CFR Part 413, Subpart H, Payment for ESRD Services. Currently, all of the Medicare payment rules for covered outpatient maintenance dialysis treatments can be found in § 413.170. We proposed to reorganize the content of Subpart H and divide existing § 413.170 into several smaller sections so that readers can more easily locate specific topics. The table outlining this change is shown below.

New section		Old section
413.170	Scope	413.170(a)
413.172	Principles of prospective payment	413.170(b)
413.174	Prospective rates for hospital-based and independent ESRD facilities	413.170(c)
413.176	Amount of payments	413.170(d)
413.178	Bad debts	413.170(e)
413.180	Procedures for requesting exceptions to payment rates	413.170(f)
413.182	Criteria for approval of exception requests	413.170(g)
413.184	Payment exception: Atypical service intensity (patient mix)	413.170(g)(1)
413.186	Payment exception: Isolated essential facility	413.170(g)(2)

New section	Old section
413.188 Payment exception: Extraordinary circumstances	413.170(g)(4)
413.190 Payment exception: Self-dialysis training costs	413.170(g)(5)
413.192 Payment exception: Frequency of dialysis	413.170(g)(6)
413.194 Appeals	413.170(h)
413.196 Notification of changes in rate-setting methodologies and payment rates	413.170(i)
413.198 Recordkeeping and cost reporting requirements for outpatient maintenance dialysis	413.174
413.200 Payment of independent organ procurement organizations and histocompatibility laboratories	413.178
413.202 Organ procurement organization (OPO) cost for kidneys sent to foreign countries or transplanted in patients other than Medicare beneficiaries.	413.179

III. Analysis of and Responses to Public Comments

In response to the August 26, 1994 proposed rule, we received nine timely items of correspondence. The specific comments and our responses are set forth below following each section describing the specific provisions of the proposed rule. The sections generally follow the order of the discussed topics in the proposed rule, with the exception of the section entitled *Bad debts* that appears last.

A. General

Comment: One commenter suggested that we update the composite rate on a regularly scheduled basis, as is done for the hospital inpatient prospective payment system rates, home health agency rates, hospice rates, and resource-based relative value scale rates.

Response: Under section 4201 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), Public Law 101-508, from January 1, 1991, onward, Congress has set the composite rates for payment for ESRD services furnished to Medicare beneficiaries. Any change would require legislative action. Thus, we have no discretion in this regard.

B. Procedures for Requesting Exceptions to Payment Rates (§ 413.180)

We proposed to redesignate the content of § 413.170(f), Procedures for requesting exceptions to payment rates, as new § 413.180. In § 413.180(d), we proposed to specify that a facility requesting an exception to its payment rate must do so within 180 days of:

- The effective date of its new composite payment rate(s);
- The effective date that HCFA opens the exceptions process; or
- The date on which an extraordinary cost-increasing event, as described in proposed §§ 413.182(c) and 413.188.

In § 413.180(f)(5), we proposed to require that the facility applying for an exception request compare its most recently completed cost report with those of prior years. Such comparisons may reveal significant changes that may indicate errors or problems with the cost or statistical data and, thus, the need for

us to more intensively review the applicable area. Any changes to cost or statistical data (for example, number of treatments) must be explained and the explanation included with the documentation supporting the exception request.

We also proposed in § 413.180(f) and § 413.182 to require that ESRD facilities provide documentation showing that their excessive costs are specifically or directly attributable to one or more of the exception criteria. As an example, for an atypical service intensity request, the facility should be able to document the excessive costs of furnishing care to patients with severe medical conditions. After submitting evidence that it treats these patients, the facility should submit records to show that a more experienced and better trained nursing staff is required to treat these patients and/or additional nursing staff time is needed. An example of the type of records that a provider should submit to document its higher nursing costs could consist of staffing schedules indicating staff and patients per shift. The facility could indicate (on the schedules) the patients with other medical conditions that were treated and the more experienced or additional staff needed to treat them. The monthly staffing schedules should represent 12 months and coincide with the actual cost reporting period of the cost report submitted with the exception request.

In § 413.180 (g) and (h), we proposed to codify in regulations the requirement under section 1881(b)(7) of the Act that specifies that unless we disapprove a composite rate exception request within 60 working days after it is filed with an intermediary, the exception is deemed approved. We require that intermediaries review and process all exception requests within 15 working days, and we process the exceptions within 45 working days.

Comment: One commenter suggested that we set three levels of documentation for exception requests in order to reduce the amount of work involved in both the preparation and review of an exception request. These three levels of documentation would

include new requests, renewal of an existing request with significant changes, and renewal of an existing request with no significant changes, respectively. The first level (new requests) would incorporate the standard currently required for all exception requests. The second level (renewal of an existing request) would require sufficient documentation to justify any additional amounts over the amount previously granted by HCFA but would not require documentation for previously justified exceptions. The third level (renewal of an existing request with no significant changes) would require only the submission of basic data and a facility certification to demonstrate that the situation has not changed.

Response: We do not agree with the commenter that the exceptions process should be established at three different levels. Given the limited timeframe allowed by the Act to approve or deny an exception (60 working days), we do not believe it would be feasible to sort through three levels of requests and address the specific issues associated with each level. Moreover, because of the volume of exceptions we receive during each exception window, we are unable to maintain exception documentation on past windows in-house, but must store these files at the Federal Records Center. Retrieving records could significantly lengthen the time we would need to review a request.

However, we agree with the commenter that requiring facilities to file new exception requests each time a cycle is opened may be overly burdensome for those facilities where no significant changes have occurred from the previous exception cycle. Therefore, we are providing (at § 413.180(e)) a mechanism for a facility to request retention of its current exception rate. This option is only available to those facilities that can demonstrate that the circumstances under which their current exception rates were granted still apply.

Historically, these providers have been required to prepare new exception request submissions for each exception

cycle. Almost all pediatric hospitals furnishing dialysis services that apply for exceptions are granted them, and the same is true for many isolated essential facilities. To ease the repetitive filing burden (and cost) for these types of facilities, we are providing for the continuation of prior exception amounts for qualifying facilities. Also, this provision would eliminate uncertainties concerning future payment rates.

We note that during an earlier exception cycle that opened March 1, 1991 and closed August 27, 1991, we allowed renal facilities a similar option of continuing to receive the exception payment rates approved during the preceding exception cycle (December 1, 1989 to May 29, 1990).

For each exception cycle, servicing intermediaries will inform all facilities by letter, 30 days prior to the effective date of a new exception cycle, that they can request exception payment rates approved during the preceding exception cycle. The facilities must then file a request with their servicing intermediary during the 30 days prior to the opening of the next exception cycle. This request should consist of a letter to the facility's servicing intermediary requesting the continuation of its previously approved exception amount. While no specific documentation is required with this request, the facility should provide enough information to adequately demonstrate that the circumstances under which the previous exception was granted have not changed. For example, for all exception requests facilities should document that its cost per treatment is higher than its composite payment rate, or if a facility is an isolated essential facility, it should specify that no new facilities have been established nearby. This request must be filed with the intermediary before the beginning of the exception cycle. The document must be delivered during the intermediary's regular business hours. Delivery of the request must be accomplished through a method that documents the time and date of receipt. A postmark or other similar mark does not serve as documentation of the time and date of receipt.

The intermediary will determine whether the renal facility still meets the exception criteria, that is, that the circumstances under which the exception was granted still exist. The intermediary will be required to make a determination on these requests within 10 working days and notify the provider and HCFA. If the intermediary determines that the renal facility meets the exception criteria, the approved exception amount would be equal to the

previously approved rate, and payment at this approved rate would continue. In cases where an exception cycle is opened because a rate increase has been approved by Congress, a facility that chooses to retain its exception rate would do so *in lieu of* any update to its composite payment rate(s).

If the facility does not continue to meet the exception criteria, the intermediary will notify the facility that, effective with the opening of the new exception cycle, the currently approved exception rate will expire and the current composite rate will go into effect. If this facility still believes it is entitled to an exception during this exception cycle, it can file a complete exception request during the remainder of the 180-day cycle.

If a renal facility does not request retention of its previously approved exception rate but still wishes an exception, the facility would be required to submit a new request during the new exception cycle. However, the approval of an exception does not assure that the amount would be equal to or higher than the currently approved exception amount. Furthermore, if the facility fails to adequately justify its exception request in accordance with the regulations and program instructions, its exception request could be denied.

Comment: One commenter suggested that we add an inflation factor to the approved rate in the second and third year during which an exception has been granted.

Response: A facility requesting approval of an exception to its composite rate must request a higher payment rate based on its projected budget estimate(s). Therefore, an approved exception rate based on projected costs would already include the inflation factor. The projected budget estimate(s) should cover the period to which the exception rate is to apply.

Comment: Several commenters suggested that we should establish regularly scheduled intervals or effective dates for the opening of the exceptions process to avoid placing an administrative burden on the provider, the intermediary, and HCFA.

Response: Currently, the exceptions process is opened each time there is a legislative change in the composite payment rate. In addition, because of the lack of any updates to the composite rates in recent years, we have opened the exceptions process three times without issuing new rates, most recently from November 1, 1993 through April 29, 1994. Only Congress has the authority to issue new rates. Deciding

whether to issue new rates has been driven by several factors, such as: (a) A review of updated ESRD audited cost and statistical data; (b) an analysis of the general growth and mix of the ESRD population in renal dialysis facilities, and (c) Congressional concerns with payment rates. Therefore, if new prospective payment rates are not issued by Congress, we will continue to determine when to open the exceptions process.

Comment: One commenter suggested that when we open the exceptions process all facilities should be eligible to apply for an exception, rather than the limited group of facilities specified in the proposed rule.

Response: In the preamble of the proposed rule, we stated that we had opened the exceptions process in situations where there had not been a rate change, permitting facilities that had received partial approvals, new facilities, or facilities that had been previously denied exceptions the chance to file for an exception. We did not mean to imply that the exceptions process is only open to these facilities. Whenever we have opened the exceptions window, all facilities have been permitted to apply for an exception, regardless of previous circumstances. However, it is only when the exception window is open that a facility may seek an exception.

Likewise, a facility wishing to retain its previously approved exception rate may only do so during the 30-day period prior to the opening of an exception cycle. We have added a sentence to § 413.180(b) to clarify this requirement.

Comment: One commenter pointed out that § 413.180(f)(5), which requires the facility to provide a comparative analysis of its costs in the most recent cost reporting period and prior years, does not specify the number of prior years' data required. The commenter believed that in order to avoid arbitrarily denying an exception request that did not contain enough comparative years, we should specify the number of years required.

Response: We agree with the commenter and have included language in § 413.180(f)(5) to state that the materials submitted to us must include a comparative analysis of the facility's costs in its most recently completed cost report with reported costs from (at least 2) prior years.

Comment: One commenter recommended that the regulation should specify the intermediary's review responsibilities during the 15 working days it has to make a recommendation to HCFA. Another commenter stated that the

intermediary's determinations regarding "completeness" invite subjective interpretations. Both commenters suggested the intermediary's 15 working day timeframe should be extended.

Response: The specific review responsibilities for intermediaries are detailed in Chapter 27 of the PRM. These responsibilities include: (a) Reviewing for completeness and accuracy the exception request, the cost report, the facility's projected costs, and any other documentation submitted by the facility to support its exception; (b) maintaining a composite rate exception log; (c) developing the content of the letter used to return an exception request to the facility; and (d) determining whether the facility's costs are reasonable and allowable. The intermediary makes the determination with respect to "completeness," and, if the renal facility fails to submit the documentation required by Chapter 27 of the PRM, the exception request is returned to the facility. Rather than specify the intermediary's responsibilities in the regulation, we believe the PRM is the appropriate place to do so. Because of the statutory deadline (section 1881(b)(7) of the Act) that an exception request is deemed approved unless we disapprove it within 60 working days, and the volume of exceptions received during an exceptions window, we believe the present timeframes (15 working days for the intermediary and 45 working days for HCFA) for processing exceptions should be maintained in order to ensure that all exceptions are processed timely.

Comment: One commenter was concerned about the implications of proposed § 413.180(l). The commenter stated that this section implies that the facility must submit an entirely new exception request if the first request (or any subsequent request) is denied. Furthermore, the commenter believed that facilities should be able to send all additional data or clarifications directly to HCFA. The commenter asserted that filing an entirely new request was unnecessary.

Response: As explained above, the intermediary has 15 working days to review the exception request for completeness and accuracy, and, if the exception request is denied because the ESRD facility did not submit the required documentation, the intermediary returns the exception request with a letter. Presently, the instructions in the PRM require that the entire exception request be returned when an exception is denied, and a new request must be submitted with the missing documentation.

We agree with the commenter that, in this situation, the submission of an entirely new exception request is not necessary. We have revised the instructions in the PRM to indicate that the denial letter from the intermediary to the ESRD facility will include a list of missing or inadequate documentation and the intermediary will request only the submission of the missing or corrected information. However, we do not agree with the suggestion that the ESRD facility should provide the additional information directly to HCFA. Because of the volume of exceptions received during an exception window, administratively it will be more efficient to have each servicing intermediary track the exceptions processed through its office and review the new information submitted by the ESRD facility. The intermediary will then forward the exceptions to us in accordance with Chapter 27 of the PRM.

Comment: One commenter suggested that because of the significant data gathering and analysis required for an exception, it should be understandable that some data elements are missed or that additional support or clarification may be required by the intermediary. The commenter suggested that providers should be permitted to submit this additional documentation after the 180-day period without an immediate exception denial. Furthermore, rate increases should be approved retroactively to the date that all detailed information is received.

Response: We disagree with the commenter. An ESRD facility that files its exception request promptly at the opening of a 180-day exception period and has its exception denied would have an additional opportunity to submit a new request before the exception period closes. If a facility chooses instead to file an exception request at or near the end of the 180-day exception period and it is not filed with all required documentation, we do not believe that it is unfair to deny the exception request. Facilities must accept the risk associated with filing their exception requests at the last minute. Since the composite rate system is a prospective payment system, we believe that it would be inconsistent to grant exceptions retroactively based on the subsequent receipt of information.

C. Criteria for Approval of Exception Requests (§ 413.182)

We proposed to redesignate the contents of § 413.170(g), Criteria for approval of exception requests, as § 413.182. In this section, we listed the criteria that may be the basis of a rate exception. These criteria are: atypical

service intensity (patient mix) (new § 413.184); isolated essential facility (new § 413.186); extraordinary circumstances (new § 413.188); self-dialysis training costs (new § 413.190); and frequency of dialysis (new § 413.192).

We received no comments on this listing. Comments on the criteria themselves are discussed in the appropriate sections below.

D. Payment Exception: Atypical Service Intensity (Patient Mix) (§ 413.184)

In the proposed rule, we specified the documentation required of a facility requesting a rate exception based on patient mix.

In § 413.184(b)(1), we proposed to require that a facility submit a list of all outpatient dialysis patients (including all home patients) treated during the most recently completed fiscal or calendar year showing:

- Patients who received transplants, including the date of the transplant;
- Patients awaiting a transplant who are medically able, have given consent, and are on an active transplant list, as well as projected transplants;
- Home patients;
- In-facility patients, staff-assisted or self-dialysis;
- Individual patient diagnoses;
- Diabetic patients;
- Patients isolated because of a contagious disease;
- Age of patients;
- Mortality rate, by age and diagnosis;
- Number of patient transfers, reasons for transfers, and any related information; and

• Total number of hospital admissions for the facility's ESRD patients, including reason and length of stay for each admission.

When adjudicating exception requests to determine if a substantial proportion of the facility's outpatient maintenance dialysis treatments involves more intense dialysis services and special dialysis procedures, we will compare the above data submitted by providers to data contained in our Patient Profile Tables. The information in the Tables is developed annually and represents information on persons with ESRD covered by Medicare.

In § 413.184(b)(2)(i), we proposed to require that a facility submit the following documentation on costs of nursing personnel (registered nurses (RNs), licensed practical nurses (LPNs), technicians and aides) incurred during the most recently completed fiscal or calendar year cost report showing:

- Amount of remuneration of each employee;
- Number of personnel;

- Amount of time spent in the dialysis unit; and
- Staff-to-patient ratio based on total hours, with an analysis of productive and nonproductive hours.

The facility must demonstrate that its nursing personnel costs have been allocated properly between each mode of care, and that the additional nursing hours per treatment are not the result of an excess number of employees in the outpatient maintenance renal dialysis department. Normally, we use staff-to-patient ratios to determine whether there is an excess number of employees assigned to a facility's dialysis department; however, we also may consider staffing schedules. Thus, an example of the type of records that a provider should submit to document its higher nursing costs could consist of staffing schedules, indicating staff and patients per shift. The facility could indicate on the schedules the patients with other medical conditions that were treated and the more experienced or additional staff needed to treat them.

When adjudicating exception requests, we will utilize the above data to determine if the facility's patients received significantly more nursing hours per treatment than patients would receive in other facilities and whether the facility's higher per treatment costs were necessitated by the special needs of the patients.

Proposed § 413.184(b)(2)(ii) included the requirement that a facility submit documentation on supply costs incurred during the most recently completed fiscal or calendar year cost report showing—

- By modality, a complete list of supplies used routinely in a dialysis treatment;
- The make and model number and component cost of each dialyzer; and
- That the supplies are prudently purchased (for example, the facility uses bulk purchase discounts when available).

The facility must demonstrate that excess supply cost per treatment is caused by the special needs of the patients and is not the result of inefficiency.

When adjudicating exception requests, we will utilize the above data to determine if the facility's patients received supplies that are medically necessary to meet their special medical needs.

Comment: One commenter believed it is an unreasonable burden to require facilities to submit 12 months of staffing schedules, since these schedules are not normally kept as permanent files and a facility might not be able to anticipate the opening of an exception window.

The commenter suggested that 3 to 6 months of staffing schedules would be more than reasonable to sufficiently document a facility's normal staffing ratios.

Response: Staffing schedules were only mentioned in the proposed rule as an example of the type of records a provider could submit to document its higher nursing costs and/or to demonstrate that there is not an excessive number of employees assigned to a facility's dialysis department. These schedules are basic source documents representing services rendered, and we believe that renal dialysis facilities maintain these schedules. We continue to believe that it is not unreasonable for a facility to submit 12 months of staffing schedules in support of its higher nursing costs. Regardless of the nature of the supporting documentation submitted, the facility must ensure that the data adequately substantiate its higher labor costs for the entire cost reporting year.

Comment: One commenter wanted the meaning of "productive and nonproductive hours" clarified. The commenter was confused as to where activities such as educational meetings, lunch breaks, paperwork, and charting fit into the documentation of staff costs.

Response: The term "productive hours" means the amount of paid nursing staff time spent on direct (hands-on) patient care and any hours explicitly connected to patient care, such as charting. All other paid nursing staff time, such as training, education, management, holidays, vacations, sick time, and lunch breaks, is considered "nonproductive hours".

Comment: One commenter believed that serving an atypical patient population could result in cost increases in areas beyond staff and supplies. Specifically, patients with severe cardiac complications might require additional monitoring equipment, and patients with communicable respiratory diseases (such as tuberculosis) might require special ventilation systems. The commenter recommended that documented overhead costs should be included in the calculation of a higher exception rate.

Response: We agree with the commenter and have in the past approved exception amounts for overhead costs related to (a) special equipment necessary for the care of patients with other medical conditions, and (b) isolation areas required for the care of hepatitis or other patients where the facility can show that isolation is necessary. For these costs to be considered under this set of exception criteria, documentation must be

submitted demonstrating the basis of the higher costs and the incremental impact on per treatment costs. The documentation must also explain how these costs relate to the atypical patient mix exception criteria. We have added § 413.184(b)(2)(iii) to state that the facility must submit documentation on overhead costs incurred during the most recently completed cost reporting year showing—

- The basis of the higher overhead costs;
- The impact on the specific cost components; and
- The effect on per treatment costs.

Comment: One commenter suggested that we should publish a complete, detailed list of supplies used in the typical dialysis treatment, including the cost of those supplies and the volume of each that is used per treatment. The commenter recommended that the listing should be in the same format as we require the facilities to use. The commenter also stated that we must publish the components of the composite rate in order to allow appropriate comparisons, including the costs, staffing ratios, and employee mix (that is, anything that we deem to be essential in order to make the comparison).

Response: When evaluating the reasonableness of a facility's component costs shown in its exception request, we use national data and general program statistics. Chapter 27 of the PRM includes our median cost per treatment data as follows:

Cost component	Amount
Salaries	\$40.00
Supplies	33.00
Overhead, excluding employee benefits	47.00
Overhead, including employee benefits	54.00
Employee benefits	7.00
Laboratory	3.00

We do not maintain detailed breakdowns of the above cost components. The cost components were derived from audited cost reports of hospital-based and independent renal dialysis facilities. Therefore, it would be difficult for us to publish an accurate list of these components to use as comparisons.

Comment: One commenter stated that where a provider had demonstrated that higher nursing staff costs are necessary to care for the sicker patients being treated, we should also recognize the higher amount of administrative and general (A & G) costs that will be allocated through the step-down process on the hospital's cost report. The

commenter also stated that since Medicare cost reporting policy recognizes "accumulated cost" as a fair and accurate basis for allocating A & G costs for cost reporting purposes, we must consider these allocated A & G costs when adjudicating ESRD exception requests.

Response: As stated in the proposed rule, the accounting protocol used for cost reporting is separate and distinct from identifying the actual A & G costs that are directly attributable to higher nursing staff costs. For a hospital-based facility, if the direct cost of nursing staff salaries in the dialysis department increased, the A & G allocated to that department would automatically increase. This is the result of the hospital cost reporting accounting protocol, which requires A & G costs to be allocated on the basis of the accumulated costs of the other departments. Since the total A & G costs represent costs allocated to the dialysis department, they do not accurately reflect the actual A & G costs incurred as a result of the additional nursing staff salary costs.

In accordance with § 413.180(f)(3), a facility must submit materials that show that the elements of excessive costs are specifically attributable to one or more of the conditions specified by the exception criteria set forth in § 413.182. According to § 413.182, HCFA may approve exceptions to an ESRD facility's prospective payment rate if the facility demonstrates with convincing objective evidence that its total per treatment costs are reasonable and allowable under the relevant cost reimbursement principles of Part 413 and its per treatment costs, in excess of its payment rate, are directly attributable to any of the exception criteria.

Our regulations do not require that the same principles of cost allocations and cost apportionment be used to determine which costs, in excess of the payment rate, are directly attributable to the exception criteria. Moreover, a provider that is granted an exception is not automatically entitled to the same payment it would have received under cost reimbursement. The excess costs must be directly attributable to the exception criteria.

E. Payment Exception: Isolated Essential Facility (§ 413.186)

We proposed to include the requirements of existing § 413.170(g)(2) as new § 413.186, and add documentation requirements for facilities that apply for a payment rate exception based on being an isolated essential facility.

1. Isolated Facility

To be considered isolated, a facility must document that it is located outside an established Metropolitan Statistical Area (MSA) and provides dialysis to a permanent patient population as opposed to a transient patient population.

2. Essential Facility

To be considered essential, the facility must document that a substantial number of its patients cannot obtain dialysis services elsewhere without substantial additional hardship and the additional hardship the patients will incur, generally, will be in travel time and cost.

3. Cost Per Treatment

The facility must document that its cost per treatment is reasonable and explain how the facility's cost per treatment in excess of its composite rate relates to the isolated essential facility criteria. For example, if a facility incurs higher supply costs, it must identify the additional costs incurred on a per treatment basis and then relate that additional cost per treatment to the exception criteria.

4. Additional Information

The facility must also furnish, in a format that concisely explains the facility's cost and patient data to support its request, the following information:

- A list of current and requested payment rates for each modality.
- An explanation of how the facility's costs in excess of its composite rate payment are attributable to the isolated essential facility criteria.
- An explanation of any unusual geographic conditions in the area surrounding the facility.
- A copy of the latest filed cost report and a budget estimate for the next 12 months on cost report forms.
- An explanation of unusual costs reported on the facility's actual or budgeted cost reports and any significant changes in budgeted costs and data compared to actual costs and data reported on the latest filed cost report.
- The name, location of, and distance to the nearest ESRD facility.
- A list of patients, treatment modality, commuting distance, and commuting time to the current and next to nearest ESRD facility.
- The historical and projected patient-to-staff ratios and number of machines used for maintenance dialysis treatments.
- A computation of the facility's treatment capacity, computed by

dividing the maintenance treatments actually furnished by the total maintenance treatments that could have been furnished (in other words, total stations multiplied by the number of hours of operation divided by the average length of dialysis) for the year.

- The geographic boundaries and population size of the facility's service area.

Comment: One commenter sought an explanation of the basis for the existing volume of treatment criterion (redesignated § 413.186(b)(3)). The commenter also recommended the establishment of a guideline for the necessary size of a facility's permanent patient population and a guideline related to a facility's minimum utilization rate.

Response: Facilities applying for an isolated essential facility exception are required to submit information with respect to the volume of treatments in order to permit comparisons with similar facilities and to determine a facility's treatment capacity. We will review the issue of developing guidelines for permanent patient population size and minimum utilization rates to determine whether it is appropriate to establish national guidelines.

Comment: One commenter requested that we clarify the language in § 413.186(b)(4) pertaining to usage of the facility "by area residents other than the applying facility's patients."

Response: We have revised § 413.186(b)(4) to specify that in determining whether a facility qualifies for an exception based on its being an isolated essential facility, we will consider the extent to which dialysis facilities (other than the applying facility's patients) are used by area residents.

Comment: One commenter suggested that a facility could be located in an MSA but still be the only supplier of dialysis in its geographical area. The commenter recommended that § 413.186(c)(1) be revised to prevent an otherwise "isolated" and "essential" facility from being automatically denied because it is located in an MSA.

Response: We agree with the commenter that it is possible that an "isolated" facility might be located in an MSA but still qualify for an exception based on all other criteria specified in this section. We are aware of several unique situations in this country where only one dialysis facility is located in a particular area that is considered an MSA. In these situations, given the characteristics associated with most MSAs, we look more closely at whether these facilities are truly

isolated (for example, increased availability of mass transportation, better road conditions, and stronger commuting patterns).

Further, we are aware that sole community hospitals (SCHs) and isolated essential facilities are defined utilizing different criteria. SCHs and isolated essential facilities render distinct care, with SCHs responsible for normal inpatient hospital stays, and isolated essential facilities responsible for routine outpatient maintenance dialysis that can be provided by a hospital-based or independent dialysis facility. Also, SCHs are defined under 42 CFR Part 412—Prospective Payment Systems for Inpatient Hospital Services, and isolated essential facilities are defined under 42 CFR Part 413, subpart H—Payment for End-Stage Renal Disease Services. However, in one criterion, location in an MSA, the definitions are similar. Within this definition, an SCH located in an MSA is automatically disqualified from being designated as an SCH. Because of the differences between isolated essential facilities and SCHs and the fact that several isolated essential facilities are unique (as explained above) we are changing the definition for isolated essential facilities located in an MSA.

Therefore, we are revising § 413.186(c)(1) to state that to be considered isolated, we would generally require the facility to document that it is located outside an established MSA.

F. Payment Exception: Extraordinary Circumstances (§ 413.188)

We proposed to redesignate existing § 413.170(g)(4) as § 413.188.

We received no comments on this proposed change.

G. Payment Exception: Self-Dialysis Training Costs (§ 413.190)

We proposed to repeat the content of existing § 413.170(g)(5) in new § 413.190(a) and to specify the documentation that we would require of a facility requesting a rate exception under this provision. We proposed to require that a facility justify its exception request by separately identifying those elements contributing to its costs in excess of the composite training rate. In adjudicating these exception requests, we would consider the facility's total costs, cost finding, and apportionment, including its allocation methodology, to determine if costs are properly reported by treatment modality. Exception requests for a higher training rate will be granted only with respect to those cost components relating to training such as technical staff, medical supplies, and the special

costs of education (manuals and education materials). Overhead and other indirect costs do not generally form a basis for granting an exception for purposes of self-dialysis training costs.

Under § 413.190(e), we proposed that the facility must provide the following information to support its exception request:

- A copy of the facility's training program.
- Computation of the facility's cost per treatment for maintenance and training sessions, including an explanation of the cost difference between the two modalities.
- Class size and patients' training schedules.
- Number of training sessions required, by treatment modality, to train patients.
- Number of patients trained for the current year and the prior 2 years on a monthly basis.
- Projection for the next 12 months of future training candidates.
- Number and qualifications of staff at training sessions.

Proposed § 413.190(f) provided that an ESRD facility may bill Medicare for a dialysis training session only when a patient receives a dialysis treatment (which normally is three times a week). If an ESRD facility elects to train all its patients using a particular modality more often than during each dialysis treatment and, as a result, the number of actual training sessions exceeds the billable limit, the facility may request a composite rate adjustment limited to the lesser of the facility's projected training cost per treatment or calculate the cost per treatment using the minimum and maximum training sessions discussed below.

An ESRD facility may bill a maximum of 25 training sessions per patient for hemodialysis training and 15 training sessions for continuous cycling peritoneal dialysis (CCPD) and continuous ambulatory peritoneal dialysis (CAPD) training. To ensure adequate patient training, we presume a minimum number of training sessions per patient in calculating exception rates, 15 for hemodialysis and 5 for CAPD and CCPD, where the renal facility's actual experience is less than the minimum number of training sessions.

To justify an accelerated training exception request, the proposed rule required that an ESRD facility document that all training sessions provided under a particular modality are to be provided during the shorter but more condensed period. The facility must submit with the exception request a list of patients,

by modality, trained during the most recent cost report period. The list must include each beneficiary's name, age, and training status (completed, not completed, being retrained, or in the process of being trained). The total treatments from the patient list must agree with the total treatments reported on the cost report filed with the request. We proposed to deny any exception request that a facility submits without the above documentation.

For purposes of clarification, we have revised § 413.190(f)(2) to state that a facility may request an exception if the facility elects to train its patients using a particular treatment modality more often than during each dialysis treatment and, as a result, the number of its billable training dialysis sessions is less than its actual training sessions.

Comment: One commenter objected to the current criterion under which a facility must train at least five patients per year in order to qualify for a self-dialysis training exception. The commenter believed that establishing a minimum number of patients trained may serve as a disincentive for facilities to start a new home training program and may conflict with the requirement of section 1881(b)(7) of the Act and proposed § 413.174(a)(3) states that our payment policies provide incentives for increasing the use of home dialysis.

Response: This criterion was not addressed in the proposed rule. However, we do use a minimum number of three patients per modality as a qualifying criterion for a self-dialysis training exception. To determine if a facility qualifies, we use each facility's average number of patients trained for the 2 previous years (if 2 years are available). We believe each facility must have a minimum number of patients to ensure that it is operating an ongoing cost-effective training program. Based on our experience and review of this subject we determined the number to be three.

Comment: One commenter suggested that the overhead and physical plant cost components represent real, necessary, and unavoidable facility costs and should be included in the calculation of training exception rates.

Response: In the proposed rule at § 413.190(d), we stated that the higher training costs do not generally include overhead and other indirect costs. However, we agree with the commenter that it is appropriate to include overhead and physical plant costs for exception request purposes. Therefore, we have revised this section to state that "the exception requests for higher training rates are limited to those cost components relating to training such as

technical staff, medical supplies, and the special costs of education (manuals and education materials). These requests may include overhead and other indirect costs to the extent that these costs are directly attributable to the additional training costs.”

Comment: One commenter stated that under proposed § 413.190(f)(1), accelerated training exceptions evidently are based on training sessions for hemodialysis training, since hemodialysis is normally furnished three times a week. The commenter believed the regulations should also provide for exceptions for accelerated training associated with CAPD or CCPD, which are typically daily treatment modalities.

Response: The proposed rule may not have been clear with respect to exceptions related to CAPD and CCPD training. Although CAPD and CCPD are daily treatment modalities, ESRD facilities are paid for training sessions based on the equivalent of three hemodialysis treatments a week for each week that CAPD and CCPD treatments are provided. Accordingly, we are revising § 413.190(f)(1) to specify the basis for payment of training sessions for CAPD and CCPD patients. Thus, exceptions for accelerated training are considered for each modality (including CAPD and CCPD) based on the number of actual training sessions in excess of billable training sessions (three per week).

Comment: One commenter objected to our proposed requirement that every training session for a particular modality be provided during the shorter, but more condensed, training period.

Response: We have revised proposed § 413.190(f)(5) to change the requirement that “all” training sessions be provided on an accelerated basis and are instead requiring that an ESRD facility must show that “a significant number of training sessions for a particular modality are provided during a shorter, but more condensed, period.” Based on our experience and review of this subject we determined that 80 percent represents a significant number of training sessions.

H. Payment Exception: Frequency of Dialysis (§ 413.192)

We proposed to redesignate § 413.170(g)(6) as § 413.192 and add several new requirements as discussed below.

Existing § 412.170(g)(6) specifies that, to qualify for an exception to the prospective payment rate based on frequency of dialysis, the facility must have a substantial portion of outpatient

maintenance dialysis treatments furnished to patients who dialyze less frequently than three times per week. A facility that furnishes a substantial portion of outpatient maintenance dialysis services to patients who dialyze less frequently than three times per week typically has higher costs per treatment because the treatments that are furnished to these patients last longer and involve higher labor and supply costs. For a facility to qualify as having a substantial portion of outpatient maintenance dialysis treatments furnished to patients who dialyze less frequently than three times per week, a facility must be able to document that it has a decrease in treatments in excess of 15 percent and cost increases due to frequency.

To document that it furnishes a substantial number of dialysis treatments at a frequency of less than three times per week, we proposed that a facility must submit a list of patients who received outpatient dialysis treatments for the latest historical cost report that is being filed with the request. The list must indicate—

- Whether the patients are permanent, transient (vacationing patients or frequently relocating patients), or temporary;
- The medically prescribed frequency of dialysis; and
- The number of dialysis treatments that each patient received on a weekly and yearly basis and an explanation of any discrepancy between that calculation and the number of treatments reported on the facility’s cost report.

We also proposed that the facility must submit a list of patients used to project treatments. The list must indicate—

- Whether the patients are permanent, transient, or temporary;
- The medically prescribed frequency of dialysis; and
- The number of dialysis treatments that each patient is projected to receive on a weekly and yearly basis, an explanation of any discrepancy between that calculation and the number of treatments reported on the facility’s projected cost report, and an explanation for any change between prior, actual, and projected data.

In order for us to determine if the facility meets the 15 percent requirement discussed above, the following information must be submitted:

- A schedule showing the number of treatments to be furnished twice a week and the number of treatments that would have been furnished if each beneficiary were dialyzed three times a

week, including a computation of the facility’s projected cost per treatment using projected treatments based on the twice a week calculation and the three times a week calculation.

- A schedule showing the computation of the percentage decrease in the number of treatments, which must be at least 15 percent to be deemed substantial for approval of an exception.

We received no comments on these proposed provision.

I. Appeals (§ 413.194)

We proposed to redesignate existing § 413.170(h) as § 413.194. In addition, we proposed to specify that exhaustion of administrative remedies is a prerequisite for judicial review.

We did not receive any comments on these proposed changes.

J. Notification of Changes in Rate-Setting Methodologies and Payment Rates (§ 413.196)

We proposed to redesignate existing § 413.170(i) as § 413.196 with only coding and editorial changes.

We did not receive any comments on these proposed changes.

K. Recordkeeping and Cost Reporting Requirements for Outpatient Maintenance Dialysis (§ 413.198)

We proposed to redesignate existing § 413.174 as § 413.198.

We did not receive any comments on this proposed change.

L. Organ Acquisition Costs (§ 412.113)

Under § 412.113, Medicare pays for kidney, heart, liver, and lung acquisition costs incurred by transplant centers on a reasonable cost basis. Currently, Medicare-certified transplant centers compute Medicare acquisition costs for these organs on Supplemental Worksheet D-6 of the Hospital Cost Report (Form HCFA-2552). The average acquisition costs of hearts, livers, and lungs transplanted in patients other than Medicare beneficiaries are deducted from the total acquisition costs for all hearts, livers, and lungs. Medicare reimburses the remaining balance as program costs for these organs. Based on recent cost analyses, we are concerned about the high Medicare costs associated with acquiring a small number of hearts, livers, and lungs. As a result, we proposed to change the method of computing heart, liver, and lung acquisition costs to determine more accurately the costs of acquiring organs transplanted in Medicare recipients. The method we proposed for computing acquisition costs for hearts, livers, and lungs conforms to the method used for

kidney acquisition costs, which more accurately accounts for Medicare's portion of such costs, including organ wastage. The formula for payment for kidney acquisition is specified in existing § 413.179. We also proposed to revise the heading in paragraph (d) of this section by replacing the terms "heart, kidney, liver, and lung" with "organ" and revising the cross-reference to indicate that "organs are defined in § 486.302."

In the August 26, 1994 proposed rule, we made the following specific proposals:

1. Payment to Independent Organ Procurement Organizations (OPOs) and Histocompatibility Laboratories

We proposed to redesignate existing § 413.178 as § 413.200. In proposed § 413.200(b), we revised the definition of "freestanding" to provide that an OPO or a histocompatibility laboratory is freestanding unless it—

- Is subject to the control of the hospital with regard to the hiring, firing, training, and paying of employees; and
- Is considered as a department of the hospital for insurance purposes (including malpractice insurance, general liability insurance, worker's compensation insurance, and employee retirement insurance).

We also proposed to remove from the definition of "freestanding" the requirement that hospital-based OPOs service a single transplant center. Section 4009(g) of the Omnibus Budget Reconciliation Act of 1987 (Public Law 100-203) required that OPOs be designated by Medicare to include no more than one OPO per service area. As the certification process limited only one OPO to an area and some of the OPOs were hospital-based, limiting the OPO's responsibility to a single transplant center became impractical. An OPO (whether independent or hospital-based) is required to service all transplant centers in its area. Accordingly, a hospital-based OPO may not necessarily service a single transplant center.

We received no comments on this proposed revision.

2. OPO or Transplant Center Costs for Kidneys Sent to Foreign Countries or Transplanted in Patients Other Than Medicare Beneficiaries

We proposed to redesignate existing § 413.179 as § 413.202 with the changes discussed below.

We proposed to expand the applicability of redesignated § 413.202 to include hearts, livers, and lungs by making it apply to "organs" instead of "kidneys." We believed that this

revision would result in a more reasonable determination of Medicare heart, liver, and lung acquisition costs because the formula for determining kidney acquisition costs more fairly accounts for Medicare's portion of such costs, including organ wastage. We cross referred § 412.113 to § 413.202 to ensure proper cost determination.

Comment: Several commenters asserted that substituting the term "organs" for "kidneys" in redesignated § 413.202 inappropriately imposed the revised methodology for determining Medicare's share of heart, liver, and lung acquisition costs on OPOs. They argued that OPOs do not have the data necessary to allocate organs between Medicare and non-Medicare patients.

Response: We agree with the commenters that substituting the term "organs" for "kidneys" would impose the revised methodology for determining Medicare's share of heart, liver, and lung acquisition costs on OPOs. Our intention in the proposed notice was to revise the methodology for Medicare transplant centers, but the proposed revision of redesignated § 413.202 inadvertently applied to OPOs as well. Therefore, we have returned to the original language in redesignated § 413.202 by resubstituting "kidneys" for "organs" and removing any reference to transplant centers; however, this section is now only applicable to OPOs. To account for all organs acquired by all transplant centers, we have added § 413.203. In addition, we have specified that the term "organs" is defined in § 486.302.

Comment: Several commenters suggested that the payment method that we proposed to apply to heart, liver, and lung acquisition costs is not always accurate. The number of Medicare beneficiaries awaiting kidneys and receiving ancillary pretransplant services could be greater or less than the percentage of Medicare beneficiaries ultimately receiving transplants. The commenters suggested revising Supplemental Worksheet D-6 (HCFA Form 2552), so that the kidney acquisition ancillary charges can be segregated into two columns, one for Medicare beneficiary services and another for the non-Medicare patients, thereby assuring that the appropriate ancillary service costs for each payer group could be accurately identified. The other direct kidney acquisition costs such as the kidney itself, transportation costs, etc., flowing through the step-down process could be determined based on the ratio of usable kidneys transplanted into Medicare and non-Medicare patients. The commenters believed that this approach would

ensure that we would not be in violation of the requirement under section 1861(v)(1)(A) of the Act that the costs of services be borne by the appropriate payer.

Response: We will consider the suggested ancillary cost report revisions during our next review of Supplemental Worksheet D-6.

M. Payment for Erythropoietin/Epoietin (EPO) (§ 413.174(f))

Erythropoietin (EPO) is an anti-anemia drug given to dialysis patients with a specified level of anemia. Payments to ESRD facilities for EPO are based on increments of 1,000 unit doses, rounded to the nearest 100 units. Section 13566 of the Omnibus Budget Reconciliation Act of 1993 (Public Law 103-66) amended section 1881(b)(11)(B)(ii) of the Act to reduce the maximum payment for EPO from \$11 to \$10 per 1,000 units. HCFA may adjust this amount, as appropriate, within stated limits. Existing § 413.170(c)(6)(iii)(B) provides for annual publication of a **Federal Register** notice indicating whether an update in the EPO payment amount is appropriate and requesting public comment. We proposed to revise § 413.174(f) to add the statutory reference and to state that we would only publish a **Federal Register** notice proposing a revision to the EPO payment amount when we determine that an adjustment to the payment amount is necessary. We would no longer publish an annual notice.

Comment: One commenter supported our proposal to eliminate the requirement to publish an annual notice regarding EPO payment when there is no payment change. However, the commenter objected to the provision under proposed § 413.174(f)(3)(iii) that limited any EPO payment increases to the percentage increase in the implicit price deflator for the gross national product. The commenter believed that this provision is unfair to ESRD providers because the providers cannot control the cost of EPO. The commenter noted that other drugs given to dialysis patients are reimbursed based on acquisition costs or wholesale prices, or both.

Response: Proposed § 413.174(f)(3)(iii) is merely a redesignation of existing § 413.170(c)(6)(iii)(c). This provision is mandated by section 1881(b)(11)(B)(ii)(II) of the Act, which gives the Secretary authority to adjust the EPO payment rate (beginning in 1995), but limits the amount of any payment increase. Since this requirement is statutorily mandated, we do not have the authority to eliminate

this provision. However, in assessing the need for an adjustment to the EPO payment rate, we would consider the actual costs incurred by ESRD facilities for EPO. If we determined that the payment limit set by statute is inadequate to ensure access to EPO by Medicare beneficiaries, we would seek a legislative change.

N. Bad Debts (§ 413.178)

In the proposed rule, we proposed to redesignate existing § 413.178 as § 413.200 and move the requirements of existing § 413.170(e) to new § 413.178. New § 413.178 will cover the proceedings for payment and reimbursement of bad debts.

Comment: One commenter suggested that the language in proposed § 413.178, implies that ESRD facilities can be reimbursed for all Medicare bad debts incurred for all covered services provided. The commenter contended that past policy had allowed reimbursement for Medicare bad debts incurred in the provision of "composite rate" dialysis services only. Therefore, the commenter recommended that the wording be modified to clarify that only bad debts related to composite rate services are subject to reimbursement.

Response: We have not made any changes to our existing bad debt policy. Medicare bad debts for ESRD services (that is, services covered under the composite rate) will continue to be determined by calculating a facility's unrecovered reasonable costs, which represent the difference between a facility's total Medicare revenues (including beneficiaries' payments) and Medicare total reasonable costs. Payment for allowable bad debts is limited to the lesser of the unrecovered reasonable costs or the total of Medicare uncollectible deductibles and coinsurance. An example can be found in chapter 27 of the PRM. We reimburse each facility its allowable Medicare bad debts in a single lump sum payment after the facility's cost reporting period ends. As the commenter suggested, we have revised § 413.178(c) to clarify, consistent with our longstanding policy, that reimbursement for bad debts is available only for covered services under the composite rate.

IV. Provisions of Final Regulations

As discussed above, we have considered the public comments received on the August 26, 1994 proposed rule and we are adopting that rule as final with the following modifications:

- In § 413.178(c), we state that a facility must request payment for uncollectible deductible and

coinsurance amounts owed by beneficiaries by submitting an itemized list of all specific uncollectable amounts related to covered services under the composite rate.

- We have added a sentence to § 413.180(b) to clarify the requirement that a facility wishing to retain its previously approved exception rate may only do so during the 30-day period prior to the opening of an exception cycle.

- We have added § 413.180(e) to state that a facility may elect to retain its previously approved exception rate in lieu of any composite rate increase or any other exception amount if—

- (1) The conditions under which the exception was granted have not changed;

- (2) The facility files a request to retain the rate with its fiscal intermediary during the 30-day period before the opening of an exception cycle; and

- (3) The request is approved by the fiscal intermediary.

- We specify in § 413.180(f)(5) that the facility must compare its most recently completed cost report with cost reports from "(at least 2)" prior years.

- We have added new § 413.184(b)(2)(iii), stating that the facility must submit documentation on overhead costs incurred during the most recently completed fiscal or calendar year cost report showing the basis of the higher overhead costs, the impact on the specific cost components, and the effect on per treatment costs.

- We have revised § 413.186(b)(4) to clarify that in determining whether a facility qualifies for an exception based on its being an isolated essential facility, we consider other dialysis facility usage by area residents (other than the applying facility's patients).

- We have revised § 413.186(c)(1) to state that to be considered isolated, "generally" a facility is located outside an established MSA and provides dialysis to a permanent patient population.

- In § 413.190(d), we have specified that an exception request for a higher training rate may include overhead and other indirect costs to the extent that these costs are directly attributable to the additional training costs.

- In § 413.190(f)(1), we have added language to state that although CCPD and CAPD are daily treatment modalities, ESRD facilities are paid the equivalent of three hemodialysis training treatments for each week that CAPD and CCPD training treatments are provided.

- We have revised § 413.190(f)(2) to state that a facility may request an exception if the facility elects to train its

patients using a particular treatment modality more often than during each dialysis treatment and, as a result, the number of its billable training dialysis sessions is less than its actual training sessions.

- We have revised § 413.190(f)(5) to state that, to justify an accelerated training exception request, an ESRD facility must document that a "significant number of" training sessions, rather than "all" sessions for a particular modality are provided during a shorter but more condensed period.

- In redesignated § 413.198, we have revised the cross-references.

- We have made several changes related to organ acquisition costs.

- + In § 412.113(d), we revised the paragraph heading, and replaced the terms "heart, kidney, liver, and lung" with "organ". We also revised the cross-reference to indicate that "organs are defined in § 485.12".

- + In § 413.202, we revised the section title and made other technical changes.

- + We added a new § 413.203 that specifies the transplant centers' costs for organs sent to foreign countries or transplanted in patients other than Medicare beneficiaries.

- We also have made minor technical changes to the regulation text for readability and ease of use.

V. Impact Statement

HCFA has examined the impacts of this final rule as required by Executive Order 12866 and the Regulatory Flexibility Act (Public Law 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 effects; distributive impacts; and equity). The Regulatory Flexibility Act requires agencies to analyze options for regulatory relief for small businesses. For purposes of the RFA, States and individuals are not considered small entities. We do consider all hospitals and ESRD facilities as small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

A. Payment Exception Requests

The purpose of this portion of this final rule is generally to codify in regulations existing policy concerning an ESRD facility's request for an exception to its prospectively determined payment rate. This policy is contained in chapter 27 of the PRM. This final rule affects all ESRD facilities, including hospital-based and freestanding, that file a request for an ESRD exception.

Our records indicate that as of December 31, 1994, there were 2,526 renal dialysis facilities, all of which were eligible to file exception requests. Of these, 377 or 15 percent of the facilities filed exception requests during our most recent exception cycle, November 1, 1993 to April 29, 1994. Of these requests, 293 facilities were granted exceptions (mostly partially granted), and 84 were denied.

Currently, a facility whose request is granted only partially or is denied an exception may appeal this determination to the PRRB. The PRRB is bound by the statute and regulations but not by program instructions; thus, it may come to a different conclusion than if it followed program instructions. Codifying in regulations details now found in the PRM instructions will bind the PRRB to more specific bases for adjudicating an appeal of a partially denied or denied exception request.

B. Organ Acquisition Costs

In 1994, there were 72 hospitals certified to perform heart transplants, and 40 hospitals certified to perform liver transplants. These hospitals constitute less than 2 percent of all Medicare-participating hospitals. In 1994, there were 381 heart transplants and 283 liver transplants performed on Medicare beneficiaries. Although the number of Medicare transplants represents 10 percent of the total number of heart and liver transplants, a preliminary review of cost report data indicates the average Medicare acquisition cost per heart and liver is higher than the average non-Medicare acquisition cost. We believe that the current method of cost reimbursement contains the potential for transplant centers to include some non-Medicare costs in the Medicare costs.

This final rule extends the formula used to compute kidney acquisition costs to other organs, including hearts, livers, and lungs. Acquisition costs will be based on the ratio of the number of usable organs transplanted into Medicare beneficiaries to the total overall number of usable organs. This ratio will not affect our obligation to pay

allowable organ acquisition costs, but will prevent Medicare from bearing costs associated with non-Medicare procedures. Based on the number of Medicare organ transplants, we anticipate annual Medicare program savings associated with this provision of less than \$5 million. Facilities that have been correctly reporting non-Medicare acquisition costs will not be affected by this rule. Facilities that have not will find their Medicare payments reduced to better reflect Medicare's share of allowable acquisition costs.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined and certify that this final rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this final rule was not reviewed by the Office of Management and Budget.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, agencies are required to provide 60-day notice in the **Federal Register** and solicit public comments before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The information collection requirements (42 CFR 413.178, 413.180, 413.182, 413.184, 413.186, 413.188, 413.190, 413.192, and 413.194) associated with requiring ESRD facilities to provide documentation for payment exception requests are currently approved by OMB under 0938-0296, HCFA-9044, that expires on May 31, 1998.

List of Subjects**42 CFR Part 412**

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Chapter IV is amended as set forth below:

A. Part 412 is amended as follows:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

1. The authority citation for part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart H—Payments to Hospitals Under the Prospective Payment Systems

2. Section 412.113 is amended by revising paragraph (d) to read as follows:

§ 412.113 Other payments.

* * * * *

(d) *Organ acquisition.* Payment for organ acquisition costs incurred by hospitals with approved transplantation centers is made on a reasonable cost basis. The term "Organs" is defined in § 486.302 of this chapter.

B. Part 413 is amended as follows:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

1. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1861(v)(1)(a), and 1871 of the Social Security Act as amended (42 U.S.C. 1302, 1395x(v)(1)(A), and 1395hh).

2. Subpart H is revised to read as follows:

Subpart H—Payment for End-Stage Renal Disease (ESRD) Services and Organ Procurement Costs

Sec.

- 413.170 Scope.
- 413.172 Principles of prospective payment.
- 413.174 Prospective rates for hospital-based and independent ESRD facilities.
- 413.176 Amount of payments.
- 413.178 Bad debts.
- 413.180 Procedures for requesting exceptions to payment rates.
- 413.182 Criteria for approval of exception requests.
- 413.184 Payment exception: Atypical service intensity (patient mix).
- 413.186 Payment exception: Isolated essential facility.
- 413.188 Payment exception: Extraordinary circumstances.
- 413.190 Payment exception: Self-dialysis training costs.
- 413.192 Payment exception: Frequency of dialysis.
- 413.194 Appeals.
- 413.196 Notification of changes in rate-setting methodologies and payment rates.
- 413.198 Recordkeeping and cost reporting requirements for outpatient maintenance dialysis.
- 413.200 Payment of independent organ procurement organizations and histocompatibility laboratories.
- 413.202 Organ procurement organization (OPO) cost for kidneys sent to foreign countries or transplanted in patients other than Medicare beneficiaries.
- 413.203 Transplant center costs for organs sent to foreign countries or transplanted in patients other than Medicare beneficiaries.

§ 413.170 Scope.

This subpart implements sections 1881 (b)(2) and (b)(7) of the Act by—

(a) Setting forth the principles and authorities under which HCFA is authorized to establish a prospective payment system for outpatient maintenance dialysis furnished in or under the supervision of an ESRD facility approved under subpart U of part 405 of this chapter (referred to as “facility” in this section). For purposes of this section and § 413.172 through § 413.198, “outpatient maintenance dialysis” means outpatient dialysis, home dialysis, self-dialysis, and home dialysis training, as defined in § 405.2102 (f)(2)(ii), (f)(2)(iii), and (f)(3) of this chapter, and includes all items and services specified in §§ 410.50 and 410.52 of this chapter.

(b) Providing procedures and criteria under which a facility may receive an exception to the prospective payment rates; and

(c) Establishing procedures that a facility must follow to appeal its payment amount under the prospective payment system.

§ 413.172 Principles of prospective payment.

(a) Payments for outpatient maintenance dialysis are based on rates set prospectively by HCFA.

(b) All approved ESRD facilities must accept the prospective payment rates established by HCFA as payment in full for covered outpatient maintenance dialysis.

(c) HCFA publishes the methodology used to establish payment rates and the changes specified in § 413.196(b) in the **Federal Register**.

§ 413.174 Prospective rates for hospital-based and independent ESRD facilities.

(a) *Establishment of rates.* HCFA establishes prospective payment rates for ESRD facilities using a methodology that—

(1) Differentiates between hospital-based facilities and independent ESRD facilities;

(2) Effectively encourages efficient delivery of dialysis services; and

(3) Provides incentives for increasing the use of home dialysis.

(b) *Determination of independent facility.* For purposes of rate-setting and payment under this section, HCFA considers any facility that does not meet all of the criteria of a hospital-based facility to be an independent facility. A determination under this paragraph (b) is an initial determination under § 498.3 of this chapter.

(c) *Determination of hospital-based facility.* A determination under this paragraph (c) is an initial determination under § 498.3 of this chapter. For purposes of rate-setting and payment under this section, HCFA determines that a facility is hospital-based if the—

(1) Facility and hospital are subject to the bylaws and operating decisions of a common governing board. This governing board, which has final administrative responsibility, approves all personnel actions, appoints medical staff, and carries out similar management functions;

(2) Facility's director or administrator is under the supervision of the hospital's chief executive officer and reports through him or her to the governing board;

(3) Facility personnel policies and practices conform to those of the hospital;

(4) Administrative functions of the facility (for example, records, billing, laundry, housekeeping, and purchasing) are integrated with those of the hospital; and

(5) Facility and hospital are financially integrated, as evidenced by the cost report, which reflects allocation of overhead to the facility through the required step-down methodology.

(d) *Nondetermination of hospital-based facility.* In determining whether a facility is hospital-based, HCFA does not consider—

(1) An agreement between a facility and a hospital concerning patient referral;

(2) A shared service arrangement between a facility and a hospital; or

(3) The physical location of a facility on the premises of a hospital.

(e) *Add-on amounts.* If all the physicians furnishing services to patients in an ESRD facility elect the initial method of payment (as described in § 414.313(c) of this chapter), the prospective rate (as described in paragraph (a) of this section) paid to that facility is increased by an add-on amount as described in § 414.313.

(f) *Erythropoietin/Epoietin (EPO).* (1) When EPO is furnished to an ESRD patient by a Medicare-approved ESRD facility or a supplier of home dialysis equipment and supplies, payment is based on the amount specified in paragraph (f)(3) of this section.

(2) The payment is made only on an assignment basis, that is, directly to the facility or supplier, which must accept, as payment in full, the amount that HCFA determines.

(3) HCFA determines the payment amount in accordance with the following rules:

(i) The amount is prospectively determined, as specified in section 1881(b)(11)(B)(ii) of the Act, reviewed and adjusted by HCFA, as necessary, and paid to hospital-based and independent dialysis facilities and to suppliers of home dialysis equipment and supplies, regardless of the location of the facility, supplier, or patient.

(ii) If HCFA determines that an adjustment to the payment amount is necessary, HCFA publishes a **Federal Register** notice proposing a revision to the EPO payment amount and requesting public comment.

(iii) Any increase in this amount for a year does not exceed the percentage increase (if any) in the implicit price deflator for gross national product (as published by the Department of Commerce) for the second quarter of the preceding year over the implicit price deflator for the second quarter of the second preceding year.

(iv) The Medicare payment amount is subject to the Part B deductible and coinsurance.

(g) *Additional payment for certain drugs.* In addition to the prospective payment described in this section, HCFA makes an additional payment for certain drugs furnished to ESRD patients by a Medicare-approved ESRD facility. HCFA makes this payment

directly to the ESRD facility. The facility must accept the allowance determined by HCFA as payment in full. Payment for these drugs is made as follows:

(1) *Hospital-based facilities.* HCFA makes payments in accordance with the cost reimbursement rules set forth in this part.

(2) *Independent facilities.* HCFA makes payment in accordance with the methodology set forth in § 405.517 of this chapter for paying for drugs that are not paid on a cost or prospective payment basis.

§ 413.176 Amount of payments.

(a) If the beneficiary has incurred the full deductible applicable under Part B of Medicare before the dialysis treatment, the intermediary pays the facility 80 percent of its prospective payment rate.

(b) If the beneficiary has not incurred the full deductible applicable under Part B of Medicare before the dialysis treatment, the intermediary subtracts the amount applicable to the deductible from the facility's prospective rate and pays the facility 80 percent of the remainder, if any.

§ 413.178 Bad debts.

(a) HCFA will reimburse each facility its allowable Medicare bad debts, as defined in § 413.80(b), up to the facility's costs, as determined under Medicare principles, in a single lump sum payment at the end of the facility's cost reporting period.

(b) A facility must attempt to collect deductible and coinsurance amounts owed by beneficiaries before requesting reimbursement from HCFA for uncollectible amounts. Section 413.80 specifies the collection efforts facilities must make.

(c) A facility must request payment for uncollectible deductible and coinsurance amounts owed by beneficiaries by submitting an itemized list that specifically enumerates all uncollectible amounts related to covered services under the composite rate.

§ 413.180 Procedures for requesting exceptions to payment rates.

(a) *Outpatient maintenance dialysis payments.* All payments for outpatient maintenance dialysis furnished at or by facilities are made on the basis of prospective payment rates.

(b) *Criteria for requesting an exception.* If a facility projects on the basis of prior year costs and utilization trends that it will have an allowable cost per treatment higher than its prospective rate set under § 413.174, and if these excess costs are attributable

to one or more of the factors in § 413.182, the facility may request, in accordance with paragraph (d) of this section, that HCFA approve an exception to that rate and set a higher prospective payment rate. However, a facility may only request an exception or seek to retain its previously approved exception rate when authorized under the conditions specified in paragraphs (d) and (e) of this section.

(c) *Application of deductible and coinsurance.* The higher payment rate is subject to the application of deductible and coinsurance in accordance with § 413.176.

(d) *Payment rate exception request.* A facility must request an exception to its payment rate within 180 days of—

(1) The effective date of its new composite payment rate(s);

(2) The effective date that HCFA opens the exceptions process; or

(3) The date on which an extraordinary cost-increasing event occurs, as specified (or provided for) in §§ 413.182(c) and 413.188.

(e) *Criteria for retaining a previously approved exception rate.* A facility may elect to retain its previously approved exception rate in lieu of any composite rate increase or any other exception amount if—

(1) The conditions under which the exception was granted have not changed;

(2) The facility files a request to retain the rate with its fiscal intermediary during the 30-day period before the opening of an exception cycle; and

(3) The request is approved by the fiscal intermediary.

(f) *Documentation for a payment rate exception request.* If the facility is requesting an exception to its payment rate, it must submit to HCFA its most recently completed cost report as required under § 413.198 and whatever statistics, data, and budgetary projections as determined by HCFA to be needed to adjudicate each type of exception. HCFA may audit any cost report or other information submitted. The materials submitted to HCFA must—

(1) Separately identify elements of cost contributing to costs per treatment in excess of the facility's payment rate;

(2) Show that the facility's costs, including those costs that are not directly attributable to the exception criteria, are allowable and reasonable under the reasonable cost principles set forth in this part;

(3) Show that the elements of excessive cost are specifically attributable to one or more conditions specified in § 413.182;

(4) Specify the amount of additional payment per treatment the facility believes is required for it to recover its justifiable excess costs; and

(5) Specify that the facility has compared its most recently completed cost report with cost reports from (at least 2) prior years. The facility must explain any material statistical data or cost changes, or both, and include an explanation with the documentation supporting the exception request.

(g) *Completion of requirements and criteria.* The facility must demonstrate to HCFA's satisfaction that the requirements of this section and the criteria in § 413.182 are fully met. The burden of proof is on the facility to show that one or more of the criteria are met and that the excessive costs are justifiable under the reasonable cost principles set forth in this part.

(h) *Approval of an exception request.* An exception request is deemed approved unless it is disapproved within 60 working days after it is filed with its intermediary.

(i) *Determination of an exception request.* In determining the facility's payment rate under the exception process, HCFA excludes all costs that are not reasonable or allowable under the reasonable cost principles set forth in this part.

(j) *Period of approval: Payment exception request.* Except for exceptions approved under §§ 413.180(e), 413.180(k), 413.182(c), and 413.188, a prospective exception payment rate approved by HCFA applies for the period from the date the complete exception request was filed with its intermediary until the earlier of the—

(1) Date the circumstances justifying the exception rate no longer exist; or

(2) End of the period during which the announced rate was to apply.

(k) *Period of approval: Payment exception request under §§ 413.182(c) and 413.188.* A prospective exception payment rate approved by HCFA under §§ 413.182(c) and 413.188 applies from the date of the extraordinary event until the end of the period during which the prospective announced rate was to apply, unless HCFA determines that another date is more appropriate. If HCFA does not extend the exception period and the facility believes that it continues to require an exception to its rate, the facility must reapply in accordance with the procedures in this section.

(l) *Denial of an exception request.* HCFA denies exception requests submitted without the documentation specified in § 413.182 and the applicable regulations cited there.

(m) *Criteria for refiling a denied exception request.* A facility that has been denied an exception request during the 180 days may file another exception request if all required documentation is filed with the intermediary by the 180th day.

§ 413.182 Criteria for approval of exception requests.

HCFA may approve exceptions to an ESRD facility's prospective payment rate if the facility demonstrates, by convincing objective evidence, that its total per treatment costs are reasonable and allowable under the relevant cost reimbursement principles of part 413 and that its per treatment costs in excess of its payment rate are directly attributable to any of the following criteria:

- (a) Atypical service intensity (patient mix), as specified in § 413.184.
- (b) Isolated essential facility, as specified in § 413.186.
- (c) Extraordinary circumstances, as specified in § 413.188.
- (d) Self-dialysis training costs, as specified in § 413.190.
- (e) Frequency of dialysis, as specified in § 413.192.

§ 413.184 Payment exception: Atypical service intensity (patient mix).

(a) To qualify for an exception to the prospective payment rate based on atypical service intensity (patient mix)—

(1) A facility must demonstrate that a substantial proportion of the facility's outpatient maintenance dialysis treatments involve atypically intense dialysis services, special dialysis procedures, or supplies that are medically necessary to meet special medical needs of the facility's patients. Examples that may qualify under this criterion are more intense dialysis services that are medically necessary for patients such as—

- (i) Patients who have been referred from other facilities on a temporary basis for more intense care during a period of medical instability and who return to the original facility after stabilization;
- (ii) Pediatric patients who require a significantly higher staff-to-patient ratio than typical adult patients; or
- (iii) Patients with medical conditions that are not commonly treated by ESRD facilities and that complicate the dialysis procedure.

(2) The facility must demonstrate clearly that these services, procedures, or supplies and its per treatment costs are prudent and reasonable when compared to those of facilities with a similar patient mix.

(3) A facility must demonstrate that—

- (i) Its nursing personnel costs have been allocated properly between each mode of care; and

- (ii) The additional nursing hours per treatment are not the result of an excess number of employees.

(b) *Documentation.* (1) A facility must submit a listing of all outpatient dialysis patients (including all home patients) treated during the most recently completed fiscal or calendar year showing—

- (i) Patients who received transplants, including the date of transplant;
- (ii) Patients awaiting a transplant who are medically able, have given consent, and are on an active transplant list, and projected transplants;
- (iii) Home patients;
- (iv) In-facility patients, staff-assisted, or self-dialysis;
- (v) Individual patient diagnosis;
- (vi) Diabetic patients;
- (vii) Patients isolated because of contagious disease;
- (viii) Age of patients;
- (ix) Mortality rate, by age and diagnosis;
- (x) Number of patient transfers, reasons for transfers, and any related information; and
- (xi) Total number of hospital admissions for the facility's patients, reason for, and length of stay of each session.

(2) The facility also must—

(i) Submit documentation on costs of nursing personnel (registered nurses, licensed practical nurses, technicians, and aides) incurred during the most recently completed fiscal year cost report showing—

- (A) Amount each employee was paid;
- (B) Number of personnel;
- (C) Amount of time spent in the dialysis unit; and

- (D) Staff-to-patient ratio based on total hours, with an analysis of productive and nonproductive hours.

(ii) Submit documentation on supply costs incurred during the most recently completed fiscal or calendar year cost report showing—

- (A) By modality, a complete list of supplies used routinely in a dialysis treatment;
- (B) The make and model number of each dialyzer and its component cost; and

- (C) That supplies are prudently purchased (for example, that bulk discounts are used when available).

(iii) Submit documentation on overhead costs incurred during the most recently completed fiscal or calendar year cost reporting year showing—

- (A) The basis of the higher overhead costs;

(B) The impact on the specific cost components; and

(C) The effect on per treatment costs.

§ 413.186 Payment exception: Isolated essential facility.

(a) *Qualifications.* To qualify for an exception to the prospective payment rate based on being an isolated essential facility—

(1) The facility must be the only supplier of dialysis in its geographical area;

(2) The facility's patients must be unable to obtain dialysis services elsewhere without substantial additional hardship; and

(3) The facility's excess costs must be justifiable.

(b) *Criteria for determining qualifications.* In determining whether a facility qualifies for an exception based on its being an isolated essential facility, HCFA considers—

(1) Local, permanent residential population density;

(2) Typical local commuting distances from medical services;

(3) Volume of treatments; and

(4) The extent that other dialysis facilities are used by area residents (other than the applying facility's patients).

(c) *Documentation.* (1) *Isolated.* Generally, to be considered isolated, the facility must document that it is located outside an established Metropolitan Statistical Area and provides dialysis to a permanent patient population, as opposed to a transient patient population.

(2) *Essential.* To be considered essential, the facility must document—

(i) That a substantial number of its patients cannot obtain dialysis services elsewhere without additional hardship; and

(ii) The additional hardship the patients will incur in travel time and cost.

(3) *Cost per treatment.* The facility must—

(i) Document that its cost per treatment is reasonable; and

(ii) Explain how the facility's cost per treatment in excess of its composite rate relates to the isolated essential facility criteria specified in paragraph (b) of this section.

(4) *Additional information.* The facility must also furnish the following information in a format that concisely explains the facility's cost and patient data to support its request:

(i) A list of current and requested payment rates for each modality.

(ii) An explanation of how the facility's costs in excess of its composite rate payment are attributable to its being an isolated essential facility.

(iii) An explanation of any unusual geographic conditions in the area surrounding the facility.

(iv) A copy of the latest filed cost report and a budget estimate for the next 12 months prepared on cost report forms.

(v) An explanation of unusual costs reported on the facility's actual or budgeted cost reports and any significant changes in budgeted costs and data compared to actual costs and data reported on the latest filed cost report.

(vi) The name, location of, and distance to the nearest renal dialysis facility.

(vii) A list of patients by modality showing commuting distance and time to the current and the next nearest renal dialysis facility.

(viii) The historical and projected patient-to-staff ratios and number of machines used for maintenance dialysis treatments.

(ix) A computation showing the facility's treatment capacity, arrived at by taking the total stations multiplied by the number of hours of operation for the year divided by the average length of a dialysis treatment.

(x) The geographic boundaries and population size of the facility's service area.

§ 413.188 Payment exception: Extraordinary circumstances.

(a) To qualify for an exception to the prospective payment rate based on extraordinary circumstances, the facility must substantiate that it incurs excess costs beyond its control due to a fire, earthquake, flood, or other natural disaster.

(b) HCFA will not grant an exception based on increased costs if a facility has chosen not to—

(1) Maintain adequate insurance protection against such losses (through the purchase of insurance, the maintenance of a self-insurance program, or other equivalent alternative); or

(2) File a claim for losses covered by insurance or utilize its self-insurance program.

§ 413.190 Payment exception: Self-dialysis training costs.

(a) *Qualifications.* To qualify for an exception to the prospective payment rate based on self-dialysis training costs, the facility must establish that it incurs per treatment costs for furnishing self-dialysis and home dialysis training that exceed the facility's payment rate for such training sessions.

(b) *Justification.* To justify its exception request, a facility must—

(1) Separately identify those elements contributing to its costs in excess of the composite training rate; and

(2) Demonstrate that its per treatment costs are reasonable and allowable.

(c) *Criteria for determining proper cost reporting.* HCFA considers the facility's total costs, cost finding and apportionment, including its allocation of costs, to determine if costs are properly reported by treatment modality.

(d) *Limitation of exception requests.* Exception requests for a higher training rate are limited to those cost components relating to training such as technical staff, medical supplies, and the special costs of education (manuals and education materials). These requests may include overhead and other indirect costs to the extent that these costs are directly attributable to the additional training costs.

(e) *Documentation.* The facility must provide the following information to support its exception request:

(1) A copy of the facility's training program.

(2) Computation of the facility's cost per treatment for maintenance sessions and training sessions including an explanation of the cost difference between the two modalities.

(3) Class size and patients' training schedules.

(4) Number of training sessions required, by treatment modality, to train patients.

(5) Number of patients trained for the current year and the prior 2 years on a monthly basis.

(6) Projection for the next 12 months of future training candidates.

(7) The number and qualifications of staff at training sessions.

(f) *Accelerated training exception.* (1) An ESRD facility may bill Medicare for a dialysis training session only when a patient receives a dialysis treatment (normally three times a week for hemodialysis). Continuous cycling peritoneal dialysis (CCPD) and continuous ambulatory peritoneal dialysis (CAPD) are daily treatment modalities; ESRD facilities are paid the equivalent of three hemodialysis treatments for each week that CCPD and CAPD treatments are provided.

(2) If an ESRD facility elects to train all its patients using a particular treatment modality more often than during each dialysis treatment and, as a result, the number of billable training dialysis sessions is less than the number of actual training sessions, the facility may request a composite rate exception, limited to the lesser of the—

(i) Facility's projected training cost per treatment; or

(ii) Cost per treatment the facility would have received in training a patient if it had trained patients only during a dialysis treatment, that is, three times per week.

(3) An ESRD facility may bill a maximum of 25 training sessions per patient for hemodialysis training and 15 sessions for CCPD and CAPD training.

(4) In computing the payment amount under an accelerated training exception, HCFA uses a minimum number of training sessions per patient (15 for hemodialysis and 5 for CAPD and CCPD) when the facility actually provides fewer than the minimum number of training sessions.

(5) To justify an accelerated training exception request, an ESRD facility must document that a significant number of training sessions for a particular modality are provided during a shorter but more condensed period.

(6) The facility must submit with the exception request a list of patients, by modality, trained during the most recent cost report period. The list must include each beneficiary's—

(i) Name;

(ii) Age; and

(iii) Training status (completed, not completed, being retrained, or in the process of being trained).

(7) The total treatments from the patient list must be the same as the total treatments reported on the cost report filed with the request.

§ 413.192 Payment exception: Frequency of dialysis.

(a) *Qualification.* To qualify for an exception to the prospective payment rate based on frequency of dialysis, the facility must establish that it has a substantial portion of outpatient maintenance dialysis treatments furnished to patients who dialyze less frequently than three times per week.

(b) *Definition.* For purposes of this section, "substantial" means the number of treatments furnished by the facility is at least 15 percent lower than the number would be if all patients dialyzed three times a week.

(c) *Limitation for per treatment payment rates.* Per treatment payment rates granted under this exception may not exceed the amount that produces weekly payments per patient equal to three times the facility's prospective composite rate, exclusive of any exception amounts.

(d) *Documentation.* To document that an ESRD facility furnishes a substantial number of dialysis treatments at a frequency less than three times per week per patient, the facility must submit the following information:

(1) A list of patients receiving outpatient dialysis treatments for the

cost report that is filed with the request. The list must indicate—

- (i) Whether the patients are permanent, transient, or temporary;
- (ii) The medically prescribed frequency of dialysis; and
- (iii) The number of dialysis treatments that each patient received on a weekly and yearly basis and an explanation of any discrepancy between that calculation and the number of treatments reported on the facility's cost report.

(2) A list of patients used to project treatments. The list must indicate—

- (i) Whether the patients are permanent, transient, or temporary;
- (ii) The medically prescribed frequency of dialysis;
- (iii) The number of dialysis treatments that each patient is projected to receive on a weekly and yearly basis, an explanation of any discrepancy between that calculation and the number of treatments reported on the facility's projected cost report, and an explanation for any change among prior, actual, and projected data.

(3) A schedule showing the number of treatments to be furnished twice a week and the number of treatments that would have been furnished if each patient were dialyzed three times a week.

(4) A computation of the facility's projected costs per treatment using the—

- (i) Projected number of treatments furnished twice a week; and
- (ii) Number of treatments if patients dialyze three times a week.

(5) A schedule showing the computation of the percentage decrease in the number of treatments.

§ 413.194 Appeals.

(a) *Appeals under section 1878 of the Act.* (1) A facility that disputes the amount of its allowable Medicare bad debts reimbursed by HCFA under § 413.178 may request review by the intermediary or the Provider Reimbursement Review Board (PRRB) in accordance with subpart R of part 405 of this chapter.

(2) A facility must request and obtain a final agency decision prior to seeking judicial review of a dispute regarding the amount of allowable Medicare bad debts.

(b) *Other appeals.* (1) A facility that has requested higher payment per treatment in accordance with § 413.180 may request review from the intermediary or the PRRB if HCFA has denied the request in whole or in part. In such a case, the procedure in subpart R of part 405 of this chapter is followed to the extent that it is applicable.

(2) The PRRB has the authority to review the action taken by HCFA on the facility's requests. However, the PRRB's decision is subject to review by the Administrator under § 405.1875 of this chapter.

(3) A facility must request and obtain a final agency decision, in accordance with paragraph (b)(1) of this section, prior to seeking judicial review of the denial, in whole or in part, of the exception request.

(c) *Procedure.* (1) The facility must request review within 180 days of the date of the decision on which review is sought.

(2) The facility may not submit to the reviewing entity, whether it is the intermediary or the PRRB, any additional information or cost data that had not been submitted to HCFA at the time HCFA evaluated the exception request.

(d) *Determining amount in controversy.* For purposes of determining PRRB jurisdiction under subpart R of part 405 of this chapter for the appeals described in paragraph (b) of this section—

(1) The amount in controversy per treatment is determined by subtracting the amount of program payment from the amount the facility requested under § 413.180; and

(2) The total amount in controversy is calculated by multiplying the amount in controversy per treatment by the projected number of treatments for the exception request period.

§ 413.196 Notification of changes in rate-setting methodologies and payment rates.

(a) HCFA or the facility's intermediary notifies each facility of changes in its payment rate. This notice includes changes in individual facility payment rates resulting from corrections or revisions of particular geographic labor cost adjustment factors.

(b) Changes in payment rates resulting from incorporation of updated cost data or general revisions of geographic labor cost adjustment factors are announced by notice published in the **Federal Register** without opportunity for prior comment. Revisions of the rate-setting methodology are published in the **Federal Register** in accordance with the Department's established rulemaking procedures.

§ 413.198 Recordkeeping and cost reporting requirements for outpatient maintenance dialysis.

(a) *Purpose and Scope.* This section implements section 1881(b)(2)(B)(i) of the Act by specifying recordkeeping and cost reporting requirements for ESRD facilities approved under subpart U of

part 405 of this chapter. The records and reports will enable HCFA to determine the costs incurred in furnishing outpatient maintenance dialysis as defined in § 413.170(a).

(b) *Recordkeeping and reporting requirements.* (1) Each facility must keep adequate records and submit the appropriate HCFA-approved cost report in accordance with §§ 413.20 and 413.24, which provide rules on financial data and reports, and adequate cost data and cost finding, respectively.

(2) The cost reimbursement principles set forth in this part (beginning with § 413.134, Depreciation, and excluding the principles listed in paragraph (b)(4) of this section), apply in the determination and reporting of the allowable cost incurred in furnishing outpatient maintenance dialysis treatments to patients dialyzing in the facility, or incurred by the facility in furnishing home dialysis service, supplies, and equipment.

(3) Allowable cost is the reasonable cost related to dialysis treatments. Reasonable cost includes all necessary and proper expenses incurred by the facility in furnishing the dialysis treatments, such as administrative costs, maintenance costs, and premium payments for employee health and pension plans. It includes both direct and indirect costs and normal standby costs. Reasonable cost does not include costs that—

(i) Are not related to patient care for outpatient maintenance dialysis;

(ii) Are for services or items specifically not reimbursable under the program;

(iii) Flow from the provision of luxury items or services (items or services substantially in excess of or more expensive than those generally considered necessary for the provision of needed health services); or

(iv) Are found to be substantially out of line with other institutions in the same area that are similar in size, scope of services, utilization, and other relevant factors.

(4) The following principles of this part do not apply in determining adjustments to allowable costs as reported by ESRD facilities:

(i) Section 413.157, Return on equity capital of proprietary providers;

(ii) Section 413.200, Reimbursement of OPAs and histocompatibility laboratories;

(iii) Section 413.9, Cost related to patient care (except for the principles stated in paragraph (b)(3) of this section); and

(iv) Sections 413.64, Payments to providers, and §§ 413.13, 413.30, 413.35, 413.40, 413.74, and §§ 415.55

through 415.70, § 415.162, and § 415.164 of this chapter, Principles of reimbursement for services by hospital-based physicians.

§ 413.200 Payment of independent organ procurement organizations and histocompatibility laboratories.

(a) *Principle.* Covered services furnished after September 30, 1978 by organ procurement organizations (OPOs) and histocompatibility laboratories in connection with kidney acquisition and transplantation will be reimbursed under the principles for determining reasonable cost contained in this part. Services furnished by freestanding OPOs and histocompatibility laboratories, that have an agreement with the Secretary in accordance with paragraph (c) of this section, will be reimbursed by making an interim payment to the transplant hospitals using these services and by making a retroactive adjustment, directly with the OPO or laboratory, based upon a cost report filed by the OPO or laboratory. (The reasonable costs of services furnished by hospital based OPOs or laboratories will be reimbursed in accordance with the principles contained in §§ 413.60 and 413.64.)

(b) *Definitions.* For purposes of this section:

Freestanding refers to an OPO or a histocompatibility laboratory that is not—

(1) Subject to the control of the hospital with respect to the hiring, firing, training, and paying of employees; and

(2) Considered as a department of the hospital for insurance purposes (including malpractice insurance, general liability insurance, worker's compensation insurance, and employee retirement insurance).

Histocompatibility laboratory means a laboratory meeting the standards and providing the services for kidneys or other organs set forth in § 413.2171(d) of this chapter.

OPO means an organization defined in § 486.302 of this chapter.

(c) *Agreements with independent OPOs and laboratories.* (1) Any freestanding OPO or histocompatibility laboratory that wishes to have the cost of its pretransplant services reimbursed under the Medicare program must file an agreement with HCFA under which the OPO or laboratory agrees—

(i) To file a cost report in accordance with § 413.24(f) within three months after the end of each fiscal year;

(ii) To permit HCFA to designate an intermediary to determine the interim reimbursement rate payable to the

transplant hospitals for services provided by the OPO or laboratory and to make a determination of reasonable cost based upon the cost report filed by the OPO or laboratory;

(iii) To provide such budget or cost projection information as may be required to establish an initial interim reimbursement rate;

(iv) To pay to HCFA amounts that have been paid by HCFA to transplant hospitals and that are determined to be in excess of the reasonable cost of the services provided by the OPO or laboratory; and

(v) Not to charge any individual for items or services for which that individual is entitled to have payment made under section 1861 of the Act.

(2) The initial cost report due from an OPO or laboratory is for its first fiscal year during any portion of which it had an agreement with the Secretary under paragraphs (c) (1) and (2) of this section. The initial cost report covers only the period covered by the agreement.

(d) *Interim reimbursement.* (1) Hospitals eligible to receive Medicare reimbursement for renal transplantation will be paid for the pretransplantation services of a freestanding OPO or histocompatibility laboratory that has an agreement with the Secretary under paragraph (c) of this section, on the basis of an interim rate established by an intermediary for that OPO or laboratory.

(2) The interim rate will be based on the average cost per service incurred by an OPO or laboratory, during its previous fiscal year, associated with procuring a kidney for transplantation. This interim rate may be adjusted if necessary for anticipated cost changes. If there is not adequate cost data to determine the initial interim rate, it will be determined according to the OPO's or laboratory's estimate of its projected costs for the fiscal year.

(3) Payments made on the basis of the interim rate will be reconciled directly with the OPO or laboratory after the close of its fiscal year, in accordance with paragraph (e) of this section.

(4) Information on the interim rate for all freestanding OPOs and histocompatibility laboratories shall be disseminated to all transplant hospitals and intermediaries.

(e) *Retroactive adjustment.* (1) *Cost reports.* Information provided in cost reports by freestanding OPOs and histocompatibility laboratories must meet the requirements for cost data and cost finding specified in paragraphs (a) through (e) of § 413.24. These cost reports must provide a complete accounting of the cost incurred by the agency or laboratory in providing

covered services, the total number of Medicare beneficiaries who received those services, and any other data necessary to enable the intermediary to make a determination of the reasonable cost of covered services provided to Medicare beneficiaries.

(2) *Audit and adjustment.* A cost report submitted by a freestanding OPO or histocompatibility laboratory will be reviewed by the intermediary and a new interim reimbursement rate for the succeeding fiscal year will be established based upon this review. A retroactive adjustment in the amount paid under the interim rate will be made in accordance with § 413.64(f). If the determination of reasonable cost reveals an overpayment or underpayment resulting from the interim reimbursement rate paid to transplant hospitals, a lump sum adjustment will be made directly between that intermediary and the OPO or laboratory.

(f) For services furnished on or after April 1, 1988, no payment may be made for services furnished by an OPO that does not meet the requirements of part 485, subpart D of this chapter.

(g) *Appeals.* Any OPO or histocompatibility laboratory that disagrees with an intermediary's cost determination under this section is entitled to an intermediary hearing, in accordance with the procedures contained in §§ 405.1811 through 405.1833, if the amount in controversy is \$1,000 or more.

§ 413.202 Organ procurement organization (OPO) cost for kidneys sent to foreign countries or transplanted in patients other than Medicare beneficiaries.

An OPO's total costs for all kidneys is reduced by the costs associated with procuring kidneys sent to foreign transplant centers or transplanted in patients other than Medicare beneficiaries. OPOs, as defined in § 435.302 of this chapter, must separate costs for procuring kidneys that are sent to foreign transplant centers and kidneys transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final settlement by the Medicare fiscal intermediaries. Medicare costs are based on the ratio of the number of usable kidneys transplanted into Medicare beneficiaries to the total number of usable kidneys applied to reasonable costs. Certain long-standing arrangements that existed before March 3, 1988 (for example, an OPO that procures kidneys at a military transplant hospital for transplant at that hospital), will be deemed to be Medicare kidneys for cost reporting statistical purposes. The OPO must submit a request to the

fiscal intermediary for review and approval of these arrangements.

§ 413.203 Transplant center costs for organs sent to foreign countries or transplanted in patients other than Medicare beneficiaries.

(a) A transplant center's total costs for all organs is reduced by the costs associated with procuring organs sent to foreign transplant centers or transplanted in patients other than Medicare beneficiaries. Organs are defined in § 486.302 (only covered organs will be paid for on a reasonable cost basis).

(b) Transplant center hospitals must separate costs for procuring organs that are sent to foreign transplant centers and organs transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final cost settlement by the Medicare fiscal intermediaries.

(c) Medicare costs are based on the ratio of the number of usable organs transplanted into Medicare beneficiaries to the total number of usable organs applied to reasonable costs.

C. Part 414 is amended as follows:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

1. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

Subpart E—Determination of Reasonable Charges Under the ESRD Program

§ 414.313 [Amended]

2. In § 414.313(a), the reference “in § 413.170 of this chapter” is revised to read “in part 413, subpart H of this subchapter”.

§ 414.314 [Amended]

3. In § 414.314(a)(5), the reference “(§ 413.170)” is revised to read “(part 413, subpart H of this subchapter)”.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 7, 1997.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

[FR Doc. 97-21444 Filed 8-14-97; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 961210346-7035-02; I.D. 081197A]

Fisheries of the Northeastern United States; Summer Flounder Fishery; Commercial Quota Harvested for Massachusetts

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Commercial quota harvest.

SUMMARY: NMFS announces that the summer flounder commercial quota available to the Commonwealth of Massachusetts has been harvested. Vessels issued a commercial Federal fisheries permit for the summer flounder fishery may not land summer flounder in Massachusetts for the remainder of calendar year 1997, unless additional quota becomes available through a transfer. Regulations governing the summer flounder fishery require publication of this notice to advise the Commonwealth of Massachusetts that the quota has been harvested and to advise vessel and dealer permit holders that no commercial quota is available for landing summer flounder in Massachusetts.

DATES: Effective August 13, 1997, through December 31, 1997.

FOR FURTHER INFORMATION CONTACT: Dana Hartley, Fishery Management Specialist, 508-281-9226.

SUPPLEMENTARY INFORMATION: Regulations governing the summer flounder fishery are found at 50 CFR part 648. The regulations require annual specification of a commercial quota that is apportioned among the states from North Carolina through Maine. The process to set the annual commercial quota and the percent allocated to each state are described in § 648.100.

The initial total commercial quota for summer flounder for the 1997 calendar year was set equal to 11,111,298 lb (5,040,000 kg) (March 7, 1997, 62 FR 10473). The percent allocated to vessels landing summer flounder in Massachusetts is 6.82046 percent, or 757,841 lb (343,751 kg).

Section 648.100(d)(2) stipulates that any overages of commercial quota landed in any state be deducted from that state's annual quota for the following year. In the calendar year 1996, a total of 800,704 lb (363,193 kg)

were landed in Massachusetts. The amount allocated for Massachusetts landings in 1996 was 752,092 lb (328,350 kg), creating a 48,612 lb (22,050 kg) overage that was deducted from the amount allocated for landings in the Commonwealth of Massachusetts during 1997 (July 15, 1997, 62 FR 37741). The resulting 1997 quota for Massachusetts is 709,229 lb (321,701 kg).

Section 648.101(b) requires the Administrator, Northeast Region, NMFS (Regional Administrator), to monitor state commercial quotas and to determine when a state's commercial quota is harvested. The Regional Administrator is further required to publish a notice in the **Federal Register** advising a state and notifying Federal vessel and dealer permit holders that, effective upon a specific date, the state's commercial quota has been harvested and no commercial quota is available for landing summer flounder in that state. Because the available information indicates that the Commonwealth of Massachusetts has attained its quota for 1997, the Regional Administrator has determined based on dealer reports and other available information, that the Commonwealth's commercial quota has been harvested.

The regulations at § 648.4(b) provide that Federal permit holders agree as a condition of the permit not to land summer flounder in any state that the Regional Administrator has determined no longer has commercial quota available. Therefore, effective August 13, 1997, further landings of summer flounder in Massachusetts by vessels holding commercial Federal fisheries permits are prohibited for the remainder of the 1997 calendar year, unless additional quota becomes available through a transfer and is announced in the **Federal Register**. Effective the date above, federally permitted dealers are also advised that they may not purchase summer flounder from federally permitted vessels that land in Massachusetts for the remainder of the calendar year, or until additional quota becomes available through a transfer.

Classification

This action is required by 50 CFR part 648 and is exempt from review under E.O. 12286.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 11, 1997.

Gary C. Matlock,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 97-21669 Filed 8-12-97; 2:16 pm]

BILLING CODE 3510-22-F

Proposed Rules

Federal Register

Vol. 62, No. 158

Friday, August 15, 1997

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.

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

7 CFR Part 1493

Expanding Export Transactions for CCC Payment Guarantees

AGENCY: Commodity Credit Corporation (CCC), USDA.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: CCC requests comments on two options to modify the regulations found at 7 CFR part 1493, subpart B, governing CCC's Export Credit Guarantee Program (GSM-102) and Intermediate Export Credit Guarantee Program (GSM-103). One option would permit CCC to guarantee payments pursuant to sight letters of credit issued by eligible foreign banks, which letters of credit would not include deferred payment terms. The other option would permit CCC to guarantee payment of obligations of eligible foreign banks arising out of transactions not involving an export letter of credit. For example, such obligations could be created by foreign banks providing guarantees of obligations of foreign buyers, including, for example, drafts drawn on and accepted by such buyers.

CCC also welcomes and will consider comments or recommendations regarding other approaches to increasing the flexibility of these programs.

DATES: Comments are due on or before September 15, 1997.

ADDRESSES: All comments should be addressed to L.T. McElvain, Director, CCC Operations Division, Foreign Agricultural Service, U.S. Department of Agriculture, AG Stop 1035, Washington, DC 20250-1035; FAX (202) 720-2949. All comments received will be available for public inspection at the above address during regular business hours.

FOR FURTHER INFORMATION CONTACT: L.T. McElvain, Director, CCC Operations Division, Foreign Agricultural Service, U.S. Department of Agriculture, Stop 1035, Washington D.C., 20250-1035; Fax

(202) 720-2949; Telephone (202) 720-6211. The U.S. Department of Agriculture (USDA) prohibits discrimination in its programs on the basis of race, color, national origin, sex, religion, age, disability, political beliefs, and marital or familial status. Persons with disabilities who require alternative means for communication of program information (braille, large print, audiotape, etc.) should contact the USDA Office of Communications at (202) 720-5881 (voice) or (202) 720-7808 (TDD).

SUPPLEMENTARY INFORMATION:

Background

The GSM-102 and GSM-103 programs are intended to increase exports of U.S. agricultural commodities and to serve other purposes stated in subpart A of 7 CFR part 1493. Criteria for allocating the availability of credit guarantees under these programs among countries and commodities are also found in subpart. In addition, the subpart contains certain program restrictions, including a prohibition on making credit guarantees available in connection with sales to any country that the Secretary of Agriculture determines cannot adequately service the debt associated with such sales.

Since late 1980, CCC has issued payment guarantees totaling \$56.7 billion (guarantee value) under the GSM-102 program. This program covers U.S. agricultural export transactions where payments are governed by irrevocable letters of credit issued by eligible foreign banks, and credits are extended by U.S. exporters or financial institutions to such foreign banks for a maximum of three years. Since FY 1986, CCC has issued payment guarantees totaling \$2.2 billion under the GSM-103 program. In this program, which is similar to the GSM-102 program, the credit periods are for not less than three, but no more than 10, years.

The regulations for the GSM-102 and 103 programs at 7 CFR part 1493 were specifically designed to assist export transactions having at least two characteristics: (1) they are financed through foreign bank letters of credit, and (2) the foreign bank makes payment on deferred terms (credit terms being provided for either in the letter of credit or a related obligation). Under the regulations as currently written, export transactions that lack either one of these

characteristics are not eligible for GSM-102 or 103 payment guarantees. For example, transactions involving payment by sight letters of credit with no related credit obligation (i.e., no credit extended to the issuing foreign bank) are not eligible. Neither are other forms of collections involving acceptances or other forms of financial documents handled by U.S. banks that are also guaranteed by a foreign bank. Such collections may be subject to the Uniform Rules for Collections (International Chamber of Commerce (ICC) Publication 522©), in contrast to existing GSM-102/103 transactions which must involve letters of credit subject to the Uniform Customs and Practice for Documentary Credits (ICC Publication 500©).

To enable CCC to better evaluate whether to modify 7 CFR part 1493 to permit the GSM-102 and 103 programs to include a greater range of transactions for which CCC would assume foreign bank risk, it was decided to seek the views of program participants and others through this advance notice of proposed rulemaking.

Options

Option 1. Amend regulations to permit CCC to issue payment guarantees covering sight letter of credit transactions (with no credit extended to the foreign bank issuing the letter of credit).

This option would require a revision of 7 CFR 1493.10. Specifically, 7 CFR 1493.10(b) provides that CCC will consider applications for payment guarantees only in connection with export sales where the payment will be made in one of two ways:

(1) An irrevocable foreign bank letter of credit, issued in favor of the exporter, specifically stating the deferred payment terms under which the foreign bank is obligated to make payments; or

(2) An irrevocable foreign bank letter of credit, issued in favor of the exporter, that is supported by a related obligation specifically stating the deferred payment terms under which the foreign bank is obligated to pay.

To implement this option, it would be necessary to delete the requirement under (1) above that the letter of credit state deferred payment terms. Other conforming changes would have to be made to various parts of the regulations.

Possible Benefits of This Option

1. Might facilitate additional export transactions without increasing CCC's multi-year credit exposure to a country at a time when such exposure is approaching the maximum exposure established by CCC. Since payment would be due at sight, CCC's exposure would be reduced more quickly than in a transaction calling for deferred payment. As a result, more transactions could be done with a country which was nearing its CCC-established credit limitations.

2. Might increase the number of export transactions where U.S. financial institutions could reduce their letter of credit confirmation fees because of the availability of CCC's guarantee.

Possible Disadvantages of This Option

1. Might be of interest to foreign buyers and U.S. banks and exporters only when the risk of default by the issuing foreign bank is considered high and U.S. banks are unwilling to confirm letters of credit or are willing to do so only at very high fees. The rate of defaults and, therefore, CCC's costs, might be high.

2. Might duplicate insurance or guarantee coverage available from private sector firms or other U.S. Government agencies.

3. Might displace cash export sales of U.S. agricultural commodities since no credit is necessary to make the transactions workable.

Option 2. Amend regulations to permit CCC to guarantee payment of eligible foreign bank obligations in transactions calling for deferred payment but not involving an irrevocable letter of credit.

One type of transaction under this option could involve foreign bank guarantees of financial instruments, including, for example, drafts drawn on, and accepted by, foreign buyers. However, the range of possible types of transactions and foreign bank guarantees could be broader than this, and commenters are urged to be as specific and detailed as possible in proposing or opposing alternatives that might be covered by this option. CCC is aware of a bank guarantee known as an *aval*. CCC is concerned, however, that avals, although commonly used in civil law jurisdictions, are virtually unknown in American jurisprudence and may not be readily enforceable in the United States.

CCC is also especially interested in comments on whether it should require, as a condition of eligibility for a guarantee, that collections of financial and commercial documents be subject

to the Uniform Rules for Collections set forth in the International Chamber of Commerce Publication 522©", or to other requirements. In this connection, commenters may wish to state clearly their understanding of the extent of the non-documentary risk that exporters would bear in a transaction where the importer refused to accept documents despite conformity of the documents with the collection instruction. In such a case the CCC guarantee would not appear to apply because the drawee would not have incurred a payment obligation to which the foreign bank guarantee would apply. Similarly, CCC seeks comments regarding whether it should require any specific wording or content in the obligation that would be guaranteed by the foreign bank or in the foreign bank's guarantee itself.

Possible Benefits of This Option

1. Might increase U.S. agricultural exports by leveraging credits made available by the private sector.

2. New or more cost-effective export opportunities might arise by increasing the flexibility with which export transactions could be structured, with payment of credits still guaranteed by eligible foreign banks.

3. Might enable or encourage participation in GSM-102 and 103 programs by additional financial institutions, resulting in a more competitive credit environment.

Possible Disadvantage of this Option

1. Exporters might face greater problems or risks in negotiating documents should they choose to participate in these types of transactions.

Considerations Regarding Comments

CCC will consider a number of factors in reviewing comments and determining whether to implement one or both of the options, or modifications thereof.

1. GSM-102/103 Criteria. As discussed above, 7 CFR part 1493, subpart A, contains objectives and criteria for these programs. Some of these, such as the requirement that countries to which credits are to be extended must be "creditworthy", are mandated by statute. Commenters should familiarize themselves with subpart A and include a discussion of relevant regulatory provisions in their comments. They should particularly address the issue of whether transactions pursuant to the proposed options would more likely be in addition to, or would more likely displace, unassisted private sector transactions. Commenters should bear in mind that, in considering options for

additional program flexibility, CCC does not intend to relax current criteria that serve to manage program risk or protect the assets of CCC.

2. Government Performance and Results Act (GPRA). In September 1997 the government-wide provisions of the GPRA will take effect. The GPRA is a performance-based management system that is directly tied to the budget process. Under the GPRA each federal agency must present to Congress its goals, how it spends money and organizes its personnel to achieve these goals, and the extent to which it achieves its goals. Each agency must prepare a 5-year strategic plan as part of its budget submission. To incorporate new programs or an expansion of existing programs into this planning process, agencies must address such issues as how benefits will be measured, why the functions or services are not being adequately performed by the private sector, and whether the new activities will be cost-effective. Commenters are invited to address specifically these issues.

Signed at Washington, DC, on August 11, 1997.

Mary T. Chambliss,

Acting General Sales Manager,

Commodity Credit Corporation.

[FR Doc. 97-21670 Filed 8-14-97; 8:45 am]

BILLING CODE 3410-10-P

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Part 252

[INS No. 1695-95]

RIN 1115-AD95

Inspection of Alien Crewmembers; 90-Day Modified Inspection Procedure

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Proposed rule.

SUMMARY: This rule proposes to amend the Immigration and Naturalization Service (Service) regulations by codifying the Service's longstanding practice of authorizing, on a discretionary basis, multiple landing privileges for certain maritime crewmembers actively serving on board a limited number of commercial maritime cruise ships and ferries making regular trips to and from the United States. This proposed rule would codify the Service's current procedure of granting, in appropriate cases, certain crewmembers' conditional landing permits. An alien crewmember who is

granted a conditional landing permits valid for multiple entries, not to exceed an aggregate of 29 days, for the 90-day period following the crewmember's in-person inspection. This procedure enables the Service to exercise its discretionary authority to forego subsequent in-person inspections of the crewmember during the 90-day period.

DATES: Written comments must be submitted on or before October 14, 1997.

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. Please include INS number 1695-95 on your correspondence to ensure proper and timely handling. Comments are available for public inspection at the above address by calling 202-514-3048, to arrange for an appointment.

FOR FURTHER INFORMATION CONTACT: Catherine M. Paler-Amaya, Assistant Chief Inspector, Immigration and Naturalization Service, 425 I Street, NW., Room 4064, Washington, DC 20536, telephone number (202) 514-3019.

SUPPLEMENTARY INFORMATION:

Background

For more than four decades, the Service has applied a modified inspection procedure with respect to certain alien crewmembers arriving in the United States on a limited number of commercial maritime ferries and cruise ships. Under this modified inspection procedure, the Service, after conducting a full-crew in-person inspection, may excuse an inspected alien crewmember from subsequent in-person inspections upon rearrival in the United States from a foreign port during the 90-day period following the date of the alien's in-person inspection. Alien crewmembers who have not been inspected during a full-crew in-person inspection must be inspected in person at the time they seek landing privileges, and may also be granted multiple entry conditional landing permits. An alien crewmember who is granted a conditional landing permit under this procedure may not remain in this country for an aggregate of more than 29 days during the 90-day period following his or her in-person inspection.

The Service first employed this 90-day modified inspection procedure in connection with the inspection of alien crewmembers employed on ferries operating in the Great Lakes area. The procedure was subsequently expanded to include the inspection of alien crewmen employed on ferries and

maritime cruise vessels docking at U.S. ports in the northeast and southeast and, ultimately, to cruise vessels operating in the Western Hemisphere and those landing at preclearance sites in the Caribbean. This discretionary modified inspection procedure applies solely to maritime ferries and cruise ships making regularly scheduled trips to and from the United States which have an established record of compliance with the immigration laws.

Legal Background

Under section 252(a)(1) of the Immigration and Nationality Act (the Act), the Service is required to examine arriving alien crewmembers to determine their eligibility for admission as nonimmigrants under section 101(a)(15)(D) of the Act. An alien crewmember who the Service determines to be admissible may be granted a conditional landing permit to land temporarily pursuant to regulations prescribed by the Attorney General for "the period of time (not to exceed 29 days) during which the vessel on which the alien arrived remains in port, provided the immigration officer is satisfied that the crewman intends to depart on the vessel or aircraft on which he arrived" (See section 252(a)(1) of the Act). In enacting this section of the Act, Congress granted the Service considerable authority to determine the most appropriate procedure for conducting examinations of arriving alien crewmen. (See also current 8 CFR 252.1.) The recent amendments to the INA Section 235 which were enacted as part of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, Pub. L. 104-208, 110 Stat. 3009 (1996) do not fundamentally alter the Service's authority in this area. Section 235(a)(3) now clearly requires the inspection of all alien crewmen seeking admission or readmission to or transit through the United States. The 90-day modified inspection procedure satisfies this mandate because it expressly contemplates an initial in-person inspection of each crewman following which the crewman may make multiple landings under specified conditions, at the discretion of the Service and for a limited period of time.

Policy Basis for the 90-Day Modified Inspection Procedure

Based on its long experience inspecting maritime vessels, the Service has determined that, in appropriate cases, the 90-day modified inspection procedure is the most appropriate means of enforcing the immigration laws. In developing this longstanding policy, the Service has considered a variety of relevant factors, including its

experience with maritime carriers at local Ports-of-Entry, the specific nature of the maritime activities involved, the frequency of a particular vessel's arrivals from a foreign port, the vessel's record of compliance with the immigration laws, the Service's local personnel requirements, and the needs of operators of maritime ferry and cruise ships and their passengers.

In instituting this procedure, the Service has determined that, in instances involving, among other things, the regular hourly, daily, or weekly arrival of alien crewmembers on ferries and/or cruise ships known to have been in compliance with the immigration laws over extended periods of time, the costs, in terms of the Service's resources and, therefore, the Service's ability to enforce the Act, substantially exceed the marginal benefits to be gained in requiring the constant re-examination of such individuals. The Service believes that the modified inspection procedure provides the Service with ample control over the entry of such alien crewmembers while offering the Service the necessary flexibility to shift more effectively its limited personnel resources to other areas it deems more vital in carrying out its statutory responsibilities.

It should be noted that invocation of the 90-day modified inspection is entirely discretionary; the Service is not required to grant a multiple entry conditional landing permit in all cases, or to forego an in-person inspection during the 90-day period even if it has issued such a permit. In all instances, the burden is on the arriving crewmember of establish eligibility for admission under section 101(a)(15)(D) of the Act. Because each situation is unique, the Service cannot give any assurance that it will be able to provide the carrier with advance notice that it will require such an in-person inspection.

Regulatory Amendments

As previously discussed, the 90-day modified inspection procedure is fully consistent with the current statutory and regulatory scheme. Accordingly, the Service is proposing to revise 8 CFR 252.1 (d), (e), and (f) to codify the longstanding Service practice of granting conditional landing permits to certain maritime crewmen, without further examination at the discretion of the Service, during the intervening time between 90-day full-crew inspections. Codifying this procedure in the form of a regulation is also necessary to ensure complete consistency with the specific terms of the Service's regulations. To this end, the Service is proposing to

amend 8 CFR 252.1(e) to provide specifically that, in cases involving the 90-day modified inspection procedure, the Service need not enter a notation on the alien crewman's Form I-95AB following each arrival from a foreign port. The proposed regulation would also require inspectors issuing conditional landing permits pursuant to the 90-day modified inspection procedure to add a specific notation to the alien crewman's Form I-95AB, at the time of the in-person inspection, stating that the conditional landing permit is valid for multiple, landings, not to exceed an aggregate of 29 days, during the 90-day period following the in-person inspection.

Limited Scope of the 90-Day Modified Inspection Procedure

Despite the codification of this 90-day modified inspection procedure in the limited circumstances previously described, the Service believes that conducting an individual in-person examination prior to each entry is the preferable manner in which to discharge the responsibilities imposed on the Attorney General in sections 235 and 252 of the Act, in most cases.

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 this rule will not have a significant economic impact on a substantial number of small entities. This rule merely incorporates a practice of longstanding policy into the Code of Federal Regulations and ensures full consistency between the procedure and the specific language of the existing 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 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.

Paperwork Reduction Act

The information collection requirements contained in this rule have been cleared by the Office of Management and Budget under the provisions of the Paperwork Reduction Act. Clearance numbers for these collections are contained in 8 CFR 299.5, Display of control numbers.

List of Subjects in 8 CFR Part 252

Administrative practice and procedure, Aliens, Crewmen, Vessels.

Accordingly, part 252 of chapter I of title 8 of the Code of Federal Regulations is proposed to be amended as follows:

PART 252—LANDING OF ALIEN CREWMEN

1. The authority citation for part 252 is revised to read as follows:

Authority: 8 U.S.C. 1103, 1184, 1258, 1281, 1282; and 8 CFR part 2.

2. In § 252.1, paragraphs (d), (e), and (f) are revised to read as follows:

§ 252.1 Examination of crewmen.

* * * * *

(d) *Authorization to land.* The immigration officer in his or her discretion may grant an alien crewman authorization to land temporarily in the United States for:

(1)(i) Shore leave purposes during the period of time the vessel or aircraft is in the port of arrival or other ports in the United States to which it proceeds directly without touching at a foreign port or place, not exceeding 29 consecutive days, if the immigration officer is satisfied that the crewman intends to depart on the vessel or aircraft on which he or she arrived or on another vessel or aircraft of the same transportation line, and the crewman's passport is surrendered for safekeeping to the master of the arriving vessel or aircraft, or

(ii) In the case of an alien crewman serving in any capacity on board a ferry or commercial maritime cruise ship making regularly scheduled trips to and from the United States, shore leave purposes during the period of time that the crewman's assigned vessel is in the port of arrival or other ports in the United States to which the vessel proceeds directly, *provided* that the total amount of time for which the crewman has been granted authorization to land does not exceed 29 days in the aggregate during the 90-day period after the date on which the crewman has

been examined in person by an immigration officer, or

(2) The purpose of departing from the United States as a crewman on a vessel other than the one on which he or she arrived, or departing as a passenger by means of other transportation, within a period of 29 days, if the immigration officer is satisfied that the crewman intends to depart in that manner, that definite arrangements for such departure have been made, and the immigration officer has consented to the pay off or discharge of the crewman from the vessel on which the crewman arrived. A crewman granted a conditional permit to land under section 252(a)(1) of the Act and paragraph (d)(1)(i) of this section is required to depart with his or her vessel from its port of arrival and from each other port in the United States to which it thereafter proceeds coastwise without touching at a foreign port or place. However, he or she may rejoin his or her vessel at another port in the United States before it touches at a foreign port or place if he or she has advance written permission from the master or agent to do so. A crewman granted a conditional permit to land under section 252(a)(1) of the Act and paragraph (d)(1)(ii) of this section is required to depart with his or her vessel from its port of arrival and from each other port in the United States to which it thereafter proceeds coastwise without touching at a foreign port or place.

(3) Upon finding an alien crewman entitled to land under paragraph (d)(1) of this section, the examining officer shall grant the alien "D-1" nonimmigrant classification. Upon finding an alien crewman entitled to land under paragraph (d)(2) of this section, the examining officer shall grant the alien "D-2" nonimmigrant classification.

(e) *Conditional permits to land.* Unless the crewman is in possession of Form I-184 and is landed under paragraph (d)(1)(i) of this section, the immigration officer shall give each alien nonimmigrant crewman permitted to land a copy of Form I-95AB, Alien Crewmen Landing Permit, presented by the crewman, and endorsed by the immigration officer to show the date and place of examination. The immigration officer shall also indicate on each Form I-95AB the type of conditional landing permit granted. In cases where the crewman is granted authorization to land under paragraph (d)(1)(ii) of this section, the inspector shall endorse the Form I-95AB with the following legend:

Pursuant to 8 CFR 252.1(d)(1)(ii), this conditional landing permit is valid for multiple landings for an aggregate of no more than 29 days during the 90-day period following the date of your in-person examination before an officer of the Immigration and Naturalization Service (Service). You must present yourself for another in-person examination before an officer of the Service upon expiration of this 90-day period. This landing authorization is conditional, and you may be required to present yourself for an in-person examination before an officer of the Service at any time during the 90-day period for which this permit has been issued.

(f) *Change of status.* An alien nonimmigrant crewman landed pursuant to the provisions of this part shall be ineligible for any extension of stay or for a change of nonimmigrant classification under 8 CFR part 248. A crewman admitted under paragraph (d)(1) of this section may, if still maintaining status, apply for a conditional landing permit under paragraph (d)(2) of this section. The application shall not be approved unless an application on Form I-408, Application to Pay Off or Discharge Alien Crewman, filed pursuant to paragraph (h) of this section, has been approved authorizing the master or agent of the vessel on which the crewman arrived to pay off or discharge the crewman and unless evidence is presented by the master or agent of the vessel to which the crewman will be transferred that a specified position on that vessel has been authorized for him or her or that satisfactory arrangements have been completed for the repatriation of the alien crewman. If the application is approved, the crewman shall be given a new Form I-95AB endorsed to show landing authorized under paragraph (d)(2) of this section for the period necessary to accomplish his or her scheduled reshipment, which shall not exceed 29 days from the date of his or her landing, upon surrendering any conditional landing permit previously issued to him or her on Form I-95AB.

* * * * *

Dated: July 17, 1997.

Doris Meissner,

Commissioner, Immigration and Naturalization Service.

[FR Doc. 97-21708 Filed 8-14-97; 8:45 am]

BILLING CODE 4410-10-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 128-0043; FRL-5876-1]

Approval and Promulgation of State Implementation Plans; California State Implementation Plan Revision, San Joaquin Valley Unified Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to act on revisions to the California State Implementation Plan (SIP) which concern five negative declarations from the San Joaquin Valley Unified Air Pollution Control District (SJVUAPCD) for the following Oxides of Nitrogen (NO_x) source categories: Nitric and Adipic Acid Manufacturing Plants, Cement Manufacturing Plants, Asphalt Batch Plants, Iron and Steel Manufacturing Plants, and Driers. The intended effect of proposing to include these negative declarations in the SIP is to meet the requirements of the Clean Air Act, as amended in 1990 (CAA or the Act). In the Final Rules Section of this **Federal Register**, the EPA is acting on the state's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no adverse comments. A rationale for this action is set forth in the direct final rule. If no adverse comments are received in response to this proposed rule, no further activity is contemplated in relation to this rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period on this document. Any parties interested in commenting on this action should do so at this time.

DATES: Comments on this proposed rule must be received in writing by September 15, 1997.

ADDRESSES: Written comments on this action should be addressed to: Julie A. Rose, Rulemaking Office (AIR-4), Air Division, U.S. Environmental Protection Agency, Region 9, 75 Hawthorne Street, San Francisco, CA 94105-3901.

Copies of the negative declarations are available for public inspection at EPA's Region 9 office and at the following locations during normal business hours. Rulemaking Office (AIR-4), Air Division, U.S. Environmental

Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105

Air Docket (6102), U.S. Environmental Protection Agency, 401 "M" Street, SW., Washington, DC. 20460

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 "L" Street, Sacramento, CA 95812

San Joaquin Valley Unified Air Pollution Control District, 1999 Tuolumne Street, Fresno, CA 93721

FOR FURTHER INFORMATION CONTACT: Julie A. Rose, Rulemaking Section, AIR-4, Air Division, U.S. Environmental Protection Agency, Region 9, 75 Hawthorne Street, San Francisco, CA 94105-3901, Telephone: (415) 744-1184.

SUPPLEMENTARY INFORMATION: This document concerns negative declarations for five NO_x source categories from the SJVUAPCD: (1) Nitric and Adipic Acid Manufacturing Plants, (2) Cement Manufacturing Plants, (3) Asphalt Batch Plants, (4) Iron and Steel Manufacturing Plants, and (5) Driers. These negative declarations certify that there are no major sources present in the above source categories in the SJVUAPCD. They were adopted by the SJVUAPCD on September 14, 1994 and submitted to EPA on October 17, 1994 by the California Air Resources Board. For further information, please see the information provided in the Direct Final action which is located in the Rules Section of this **Federal Register**.

Authority: 42 U.S.C. 7401-7671q.

Dated: August 1, 1997.

Felicia Marcus,

Regional Administrator.

[FR Doc. 97-21693 Filed 8-14-97; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MO 033-1033; FRL-5875-6]

Approval and Promulgation of Implementation Plans; State of Missouri

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to approve State Implementation Plan (SIP) revisions submitted by the state of Missouri to create a new statewide fugitive dust rule. In addition, the EPA is proposing to rescind four area specific

fugitive dust rules which the new rule replaces. The new fugitive dust rule provides a consistent and enforceable mechanism to help maintain compliance with the National Ambient Air Quality Standards (NAAQS) for particulate matter.

DATES: Comments must be received on or before September 15, 1997.

ADDRESSES: Comments may be mailed to Aaron J. Worstell, Environmental Protection Agency, Air Branch, 726 Minnesota Avenue, Kansas City, Kansas 66101.

FOR FURTHER INFORMATION CONTACT: Aaron J. Worstell at (913) 551-7787.

SUPPLEMENTARY INFORMATION:

I. Background

Missouri originally adopted the new fugitive dust rule (10 CSR 10-6.170) on June 28, 1990, and it became effective on November 30, 1990. It was not submitted to the EPA at that time, but was subsequently amended by the state and submitted to the EPA on November 20, 1996 (with supplemental information provided on February 24, 1997). Missouri adopted the amended rule on June 27, 1996, and it became effective on October 30, 1996.

In conjunction with Missouri's request for SIP approval of 10 CSR 10-6.170, the EPA is addressing Missouri's submittal of September 25, 1990, requesting rescission of four area specific fugitive dust rules (10 CSR 10-2.050, 3.070, 4.050, and 5.100).

The primary purpose of the new fugitive dust rule is to "restrict the emission of particulate matter to the ambient air beyond the premises of origin." In more general terms, the rule limits fugitive dust emissions onto adjacent property and to the atmosphere. The rule achieves this by prohibiting the deposition of particulate matter onto surrounding property and by restricting visible emissions. In addition, the rule specifies several typical fugitive dust measures to be employed to prevent emissions to surrounding property. Finally, the rule provides specific exceptions where the state has determined that fugitive dust controls would not be practical (e.g., agricultural operations such as tilling).

The impetus for the development of Missouri rule 10 CSR 10-6.170 was the need for a consistent, statewide rule that serves to protect the particulate matter NAAQS by limiting fugitive dust emissions. Prior to the initial development of this rule in 1990, the following four area specific rules regulated fugitive emissions in Missouri: 10 CSR 10-2.050, Preventing Particulate Matter From Becoming

Airborne (Kansas City); 10 CSR 10-3.070, Restriction of Particulate Matter From Becoming Airborne (Outstate); 10 CSR 10-4.050, Preventing Particulate Matter From Becoming Airborne (Springfield); and 10 CSR 10-2.050, Preventing Particulate Matter From Becoming Airborne (St. Louis). The EPA approved these rules (see 37 FR 10842) as part of the original SIP submission in 1972.

The current fugitive dust SIP rules are not only applicable only in limited areas, but they also contain varying applicability provisions, enforcement mechanisms, and exceptions. Rule 10 CSR 10-5.010, applicable only in St. Louis, prohibits particulate matter from becoming airborne but does not state specific visual or property line standard limitations. Rule 10 CSR 10-4.050, applicable only in Springfield, introduces visible limitations plus a complaint-based enforcement mechanism. Rules 10 CSR 10-3.070 and 10 CSR 10-2.050, the Outstate rule and Kansas City rule, respectively, include both visible and property line standard limitations. The visible limitations for these latter two rules apply to dust-containing particles greater than 40 microns in diameter. Thus, the two rules are not completely in concert with the more recent particulate matter standard that includes only those particles nominally smaller than 10 microns. The property line standard limits the concentration of particulate matter at any inhabited place to specified concentrations as determined by a high-volume sampler or soiling index. All four rules require reasonable control measures for certain activities, but only three provide specific exceptions from the rule. This lack of consistency among the SIP rules is potentially confusing for industries with multiple sources or portable sources, complicating compliance efforts.

While Missouri has rescinded the rules from state regulation, they continue to be active elements of the SIP and are therefore federally enforceable. The new fugitive dust rule will reconcile the Missouri state regulations and the SIP. In addition, the new rule improves upon the existing SIP rules since it: (1) Requires reasonable control measures on a broader range of fugitive dust sources; (2) abandons the 40-micron qualification and property line standards, making the rule consistent with current NAAQS and simplifying compliance determinations for sources and regulatory agencies; and (3) abandons the complaint-based enforcement mechanism present in some of the rules. Overall, this rule will

help to maintain compliance with the particulate matter NAAQS in Missouri.

The EPA believes that the revised rule is approvable because it strengthens the existing SIP by making the fugitive dust control requirements consistent, and by clarifying the actions which constitute prohibited emissions, and the types of measures which must be implemented to minimize or eliminate such emissions.

II. Proposed Action

The EPA is proposing to approve revisions to the SIP submitted by the state of Missouri on September 25, 1990, November 20, 1996, and February 24, 1997. These revisions include the addition of Rule 10 CSR 10-6.170, Restriction of Particulate Matter to the Ambient Air Beyond the Premises of Origin; and the rescission of 10 CSR 10-2.050, Preventing Particulate Matter From Becoming Airborne (Kansas City), 10 CSR 10-3.070, Restriction of Particulate Matter From Becoming Airborne (Outstate), 10 CSR 10-4.050, Preventing Particulate Matter From Becoming Airborne (Springfield), and 10 CSR 10-2.050, Preventing Particulate Matter From Becoming Airborne (St. Louis).

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any SIP. Each request for revision to the SIP shall be considered separately in light of specific technical, economic, and environmental factors, and in relation to relevant statutory and regulatory requirements.

III. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget has exempted this regulatory action from Executive Order 12866 review.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, the 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, the 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 Clean Air Act (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, the Administrator certifies that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-state relationship under the CAA, preparation of a regulatory flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The CAA forbids the EPA to base its actions concerning SIPs on such grounds (*Union Electric Co. v. U.S. E.P.A.*, 427 U.S. 246, 256–66 (S.Ct. 1976); 42 U.S.C. 7410(a)(2)).

C. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 (“Unfunded Mandates Act”), signed into law on March 22, 1995, the 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 private sector, of \$100 million or more. Under section 205, the 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 the EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

The EPA has determined that the approval action proposed 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 preexisting requirements under state or local law and imposes no new requirements. Accordingly, no additional costs to state, local, or tribal governments, or to the private sector, result from this action.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401–7671q.

Dated: August 4, 1997.

Michael J. Sanderson,

Acting Regional Administrator.

[FR Doc. 97–21695 Filed 8-14-97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[IA 031–1031; FRL–5875–5]

Approval and Promulgation of Implementation Plans; State of Iowa

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to approve the State Implementation Plan (SIP) submitted by the state of Iowa to achieve attainment of the primary National Ambient Air Quality Standard (NAAQS) for sulfur dioxide (SO₂) for Muscatine County, Iowa. The SIP was submitted to satisfy the requirements of section 110 and part D of title I of the Clean Air Act (Act), and regulates certain sources of SO₂ emissions in Muscatine, Iowa. The effect of the EPA's proposed action is to make this revision to the Iowa SIP federally enforceable.

DATES: Comments must be received on or before September 15, 1997.

ADDRESSES: Comments may be mailed to Wayne Kaiser, Environmental Protection Agency, Air Planning and Development Branch, 726 Minnesota Avenue, Kansas City, Kansas 66101.

FOR FURTHER INFORMATION CONTACT: Wayne Kaiser at (913) 551–7603.

SUPPLEMENTARY INFORMATION:

I. Background

On March 10, 1994, the EPA published a document in the **Federal Register** (59 FR 11193) designating a portion of Muscatine County, Iowa, nonattainment for SO₂. Additional information on the events leading to nonattainment designation are contained in the Technical Support Document (TSD) which accompanied that document.

Areas designated nonattainment are subject to section 110 and part D of title I of the Act. On June 13, 1996, and April 25, 1997, the state of Iowa submitted information satisfying these requirements. An evaluation of the adequacy of this submittal with the Federal requirements is discussed below.

II. Description and Analysis of State Submittal

In 1991 and 1992 there were violations of the primary SO₂ NAAQS at one of three state air monitors in Muscatine, Iowa. This resulted in designation of a portion of Muscatine County as nonattainment in 1994. The state determined that there were two

major emission sources contributing to the violations of the NAAQS. They were Grain Processing Corporation (GPC), a wet grain milling facility, and Muscatine Power and Water (MPW), a municipal power plant. In the course of modeling the impacts of these emission sources, it was also determined that a third source, Monsanto Corporation, contributed to a modeled violation of the SO₂ NAAQS in the vicinity of its own facility.

The state of Iowa's Department of Natural Resources negotiated emission reductions with GPC, MPW, and Monsanto. The reductions were incorporated into revised construction permits. These permits have been submitted as a part of the section 110 SIP revision and thus will be federally enforceable when approved by the EPA.

The normal process for establishing a control strategy for an area where a NAAQS violation has occurred is to conduct an air dispersion modeling analysis to determine the degree of emissions reductions required by the sources contributing to the monitored violations.

The NAAQS violations occurred at the Musser Park monitor, which is located north of and nearest to the GPC facility. Two additional monitors, one located further north of the sources, and one located to the south near MPW, have never recorded any violations of the NAAQS.

Dispersion modeling performed by the state using the EPA's Industrial Source Complex (ISC) model significantly under predicted monitored values at the Musser Park monitor, but was highly accurate at the other downwind monitoring site. Consequently, the state initially used an alternative methodology, roll-back analysis, to estimate emission rates needed to attain the NAAQS at the Musser Park monitoring site. A roll-back analysis takes a monitored ambient exceedance recorded during a specific set of facility operating conditions and determines the amount of the exceedance due to each of the source's SO₂ emitting operations in use at that time. The estimates are then linearly “rolled back” to acceptable SO₂ emission limits which provide for attainment of the NAAQS under that set of operating conditions. Ultimately, the state, GPC, and MPW negotiated reductions of allowable emissions of 24 percent and 60 percent, respectively, and reductions of actual emissions of 4 percent and 13 percent, respectively. These emission reductions were incorporated into revised construction permits for each source. These permits are proposed for approval as part of this

SIP revision and thus will be federally enforceable. The TSD for this action contains further information on the modeling analysis and the establishment of the final emission limits.

Although the ISC model was not sufficiently accurate to be the basis for the control strategy at GPC and MPW, it was judged to be reliable for predicted emissions in the vicinity of the Monsanto facility. Modeling here indicated one small area of nonattainment on plant property to which the public had access. Monsanto agreed to accept emission limits and operating conditions in its permits to eliminate the modeled exceedances of the SO₂ NAAQS.

The emission limits imposed upon the sources are contained in the following permits:

GPC Permits dated September 18, 1995:

#95-A-374; Boilers 1,2,3,5,6,7, #74-A-015-S; Source 97, Wet Milling No. 3 Germ Drier, #79-A-194-S; Source 15, Wet Milling Nos. 1 and 2 Germ Driers, #79-A-195-S; Source 126, Wet Milling No. 4 Germ Drier. Permit #95-A-374 contains the requirement for the installation of a continuous emission monitor (CEM) on the stack servicing the permitted boilers.

MPW Permits dated September 14, 1995: #74-A-175-S; Boiler 7, #95-A-373; Boiler 8. Permit #74-A-175 requires the installation of a CEM on boiler stack 7. The CEMs provide for continuous measurement of SO₂ emissions and the subsequent determination of compliance with the permit emission limits. All permits contain the state's standard notification, recordkeeping, and reporting requirements.

Monsanto Permits dated July 18, 1996: #76-A-265-S3; B-6 Boiler, and #76-A-161-S3; B-7 Boiler.

III. Nonattainment Plan Provisions (Part D, Section 172(c))

The following discusses how the submission complies with the pertinent provisions of the General Preamble for Implementation of title I of the 1990 Amendments and the *SO₂ Guideline Document*, as well as section 172(c) of the Act, which sets forth the requirements for part D SO₂ SIPs.

Section 172(c)(1)—In General. The plan complies with the requirements to implement reasonably available control measures by providing for expeditious attainment of the SO₂ NAAQS through the emission limits imposed on the sources by enforceable permits.

Section 172(c)(2)—Reasonable Further Progress (RFP). Section 171(l) of the

amended Act defines RFP as “such annual incremental reductions in emissions of the relevant air pollutant as are required by (part D) or may reasonable be required by the EPA for the purpose of ensuring attainment of the applicable national ambient air quality standard by the applicable date.” As discussed in the General Preamble for SO₂ (57 FR 13547), there is usually a single “step” between precontrol nonattainment and postcontrol attainment. Therefore, for SO₂, with its discernible relationship between emissions and air quality and significant and immediate air quality improvement, RFP is construed as “adherence to an ambitious compliance schedule.”

The state has met the requirement to implement reasonably available control measures and RFP by providing for expeditious attainment of the SO₂ NAAQS through the establishment of emissions limits and operating restrictions imposed on the sources by the state construction permits submitted as part of the state plan. Implementation plans required under section 191(a) shall provide for attainment as expeditiously as practicable but no later than five years from the date of the nonattainment designation, in this case by March 1999. However, the state permits required compliance (and attainment) by March 15, 1996. The sources met this compliance date, and the EPA believes that this date was as expeditious as practicable.

Section 172(c)(3)—Inventory. This section of the Act requires that nonattainment plan provisions include a comprehensive, accurate, current inventory of actual emissions from all sources of relevant pollutants in the nonattainment area. The emission inventory also should include a comprehensive, accurate, and current inventory of allowable emissions in the area.

A detailed emission inventory was included in the state's submittal. In order to better quantify actual emission from the 100 “nontraditional” sources at GPC, source testing was conducted on two occasions on a number of representative emission points. In addition to the four major sources in the area, an emissions inventory was obtained for modeling purposes from three additional minor sources in Muscatine, and from 36 sources outside of Muscatine but within 50 kilometers.

Section 172(c)(5)—Permits for New and Modified Major Stationary Sources. Section 172(c)(5) and section 173 of the amended Act contains SIP requirements for state construction permitting programs. Any new or modified major

stationary source constructed in a nonattainment area must comply with the state submitted and federally approved New Source Review (NSR) Program. The state has an approved NSR program. However, revisions were required to make the state rules compliant with the 1990 Amendments. The state adopted revisions and the EPA approved them in **Federal Register** documents dated June 23, 1995, and October 30, 1995. The EPA action proposing approval of the state's emission offset rule has been published and a final action is pending.

Section 172(c)(6)—Other Measures. This section states that SIP provisions shall include enforceable emission limitations, and such other control measures, means or techniques, as well as schedules and timetables for compliance as may be necessary, to provide for attainment by the applicable attainment date.

The state SIP provides for expeditious attainment of the SO₂ NAAQS through the emission limits and operating restrictions that are set forth in the permits issued by the state. The emission reductions contained in these documents should ensure that the area continues to attain the NAAQS.

Section 172(c)(7)—Compliance with Section 110(a)(2). This section contains general requirements for nonattainment plans. The state has met these requirements. The SIP contains enforceable permits which ensure attainment of the NAAQS. The state has committed to continue its existing ambient monitoring network; it has an approved parts C and D permit program (final approval of the state's emission offset rule is pending); and it has authority to prevent construction of a source which will contribute significantly to nonattainment in, or interfere with maintenance by, any other state with respect to the NAAQS. It also has demonstrated it has adequate personnel, funding, and authority under state law to carry out the provisions of the SIP. With respect to section 110(a)(2)(K), under which the EPA generally requires modeling in the case of SO₂ and other pollutants (to demonstrate attainment as required by other provisions of section 110(a) and part D), the EPA notes that the ISC model used by the state has been shown to under predict ambient SO₂ concentrations at the Musser Park monitor on known exceedance days. Therefore, as described in more detail above, a negotiated reduction of the permitted emission limits was established.

Section 172(c)(8)—Equivalent Techniques. This section provides that

the EPA may allow the state to use equivalent modeling, emission inventory, and planning procedures in its SIP unless the EPA determines they are less effective than procedures approved by the Administrator. Since attainment of the SO₂ NAAQS could not be demonstrated for all portions of the nonattainment area by modeling (for technical reasons described above and in more detail in the TSD), reductions in both allowable and actual limits were determined for the affected sources based generally on rollback calculations. The EPA believes that this procedure is no less effective than other procedures approved by the Administrator since it results in enforceable reductions in both potential and actual emissions. In addition, although not a basis for approval of the attainment demonstration, the EPA notes that no monitored violations of the NAAQS have been recorded since the reductions have been implemented.

Section 172(c)(9)—Contingency Measures. For SO₂ programs, the EPA interprets “contingency measures” to mean that the state agency has a comprehensive program to identify sources of violations of the SO₂ NAAQS and to undertake an aggressive follow-up for compliance and enforcement, including expedited procedures for establishing enforceable consent agreements pending adoption of revised SIPs.

The state has a comprehensive program to identify sources of violations of the SO₂ NAAQS and to undertake an aggressive follow-up for compliance and enforcement. The state has statutory authority to address any exceedances and resultant violations of the NAAQS that may be identified.

The state will continue to maintain the network of the three SO₂ ambient air monitoring stations in the nonattainment area. The state is committed to quickly identifying when exceedances occur and evaluating which sources may be contributing to such occurrences. Direct source monitoring, using CEMs as required in the permits issued to MPW and GPC under this plan, is designed to ensure that the emissions limitations in the permit are not exceeded. Reporting requirements established in those permits provide the state with a mechanism to consistently monitor the operations of those sources.

Section 176(c)—Conformity. The EPA promulgated final general conformity regulations on November 30, 1993. These regulations require the states to adopt general conformity provisions in the SIPs for areas designated

nonattainment or subject to a maintenance plan approved under section 175A of the Act. The state submitted its general conformity SIP, which the EPA approved on October 25, 1995. The state is not subject to the transportation conformity requirements.

The state complied with the procedural requirements for submittal of SIPs pursuant to sections 110(a) and 110(l). The state provided for public notice and comment as required. The permits were approved by the Iowa Environmental Protection Commission. The SIP and related documentation was submitted by the governor's designee to the EPA on June 13, 1996, and April 25, 1997.

The SIP submittal was reviewed by the EPA to determine completeness in accordance with the completeness criteria set out in 40 CFR part 51, appendix V. The submittal was found complete and the state was so notified by an EPA letter dated July 16, 1996.

IV. Proposed Action

The EPA is proposing to approve a revision to the state SIP which incorporates emission restrictions and limitations on major SO₂ sources in Muscatine, Iowa, for the purpose of assuring attainment and maintenance of the SO₂ NAAQS. The enforceable permit conditions have been in effect since March 15, 1996. There have been no exceedances of the NAAQS since September 1995.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any SIP. Each request for revision to the SIP shall be considered separately in light of specific technical, economic, and environmental factors, and in relation to relevant statutory and regulatory requirements.

V. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget has exempted this regulatory action from Executive Order 12866 review.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, the 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, the 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, the Administrator certifies that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-state relationship under the CAA, preparation of a regulatory flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The CAA forbids the EPA to base its actions concerning SIPs on such grounds (*Union Electric Co. v. U.S. E.P.A.*, 427 U.S. 246, 256–66 (S.Ct. 1976); 42 U.S.C. 7410(a)(2)).

C. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 (“Unfunded Mandates Act”), signed into law on March 22, 1995, the 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 private sector, of \$100 million or more. Under section 205, the 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 the EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

The EPA has determined that the approval action proposed 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 preexisting requirements under state or local law, and imposes no new requirements. Accordingly, no additional costs to state, local, or tribal governments, or to the private sector, result from this action.

Authority: 42 U.S.C. 7401–7671q.

Dated: July 24, 1997.

William Rice,

Acting Regional Administrator.

[FR Doc. 97–21696 Filed 8-14-97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52**

[TN-142-9727(b); FRL-5873-1]

Approval and Promulgation of Revisions to Tennessee SIP Chapter 1200-3-5 Visible Emissions**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Proposed rule.

SUMMARY: On October 4, 1994 Tennessee submitted, through the Department of Environment and Conservation, a new chapter 1200-3-5 Visible Emissions to replace the existing chapter 1200-3-5 Visible Emissions found in the Tennessee State Implementation Plan (SIP). These revisions include amendments and repeals of existing rules. In the final rules section of this **Federal Register**, the EPA is approving the revision as a direct final rule without prior proposal because the EPA views this as a noncontroversial revision amendment and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to that direct final rule no further activity is contemplated in relation to this proposed rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period on this document. Any parties interested in commenting should do so at this time.

DATES: To be considered, comments must be received by September 15, 1997.

ADDRESSES: Written comments on this action should be addressed to Randy Terry at the Environmental Protection Agency, Region 4 Air Planning Branch, 61 Forsyth Street, Atlanta, Georgia 30303.

Copies of documents relative to this action are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day and reference file TN 142-01-9727. The Region 4 office may have additional background documents not available at the other locations.

Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

Environmental Protection Agency, Region 4 Air Planning Branch, 61 Forsyth Street, SW., Atlanta, Georgia 30303.

Department of Environment and Conservation, 9th Floor L & C Annex, 401 Church Street, Nashville, TN 37243-1531.

FOR FURTHER INFORMATION CONTACT: Randy Terry, Regulatory Planning Section, Air Planning Branch, Air, Pesticides & Toxics Management Division, Region 4 Environmental Protection Agency, 61 Forsyth Street, SW., Atlanta, Georgia 30303. The telephone number is (404) 562-9032.

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule which is published in the rules section **Federal Register**.

Dated: July 9, 1997.

Michael V. Peyton,

Acting Regional Administrator.

[FR Doc. 97-21698 Filed 8-14-97; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 300**

[FRL-5874-3]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of intent to delete Northwest Transformer South Harkness Street site from the National Priorities List Update; request for comments.

SUMMARY: The Environmental Protection Agency (EPA), Region 10, announces its intent to delete the Northwest Transformer South Harkness Street Site in Everson, Washington, from the National Priorities List (NPL) and requests public comment on this proposed action. The NPL constitutes Appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended. EPA and the State of Washington Department of Ecology (Ecology) have determined that the Site poses no significant threat to public health or the environment and, therefore, further remedial measures pursuant to CERCLA are not appropriate.

DATES: Comments concerning this Site may be submitted on or before September 15, 1997.

ADDRESSES: Comments may be mailed to: Timothy H. Brincefield, Environmental Protection Agency, 1200 Sixth Avenue, Mail Stop ECL-111, Seattle, WA 98101.

Comprehensive information on this Site is available through the Region 10 public docket which is available for viewing at the NW Transformer South Harkness Site information repositories at the following locations:

Whatcom County Public Library, Kirsch Drive, Everson, Washington 98247.

United States Environmental Protection Agency, Region 10, Office of Environmental Cleanup—Records Center, Attn: Bob Phillips, 1200 Sixth Avenue, Mail Stop ECL-110, Seattle, Washington 98101.

FOR FURTHER INFORMATION CONTACT: Timothy H. Brincefield, U.S. EPA Region 10, 1200 Sixth Avenue, Mail Stop ECL-111, Seattle, Washington 98101, (206) 553-2100.

SUPPLEMENTARY INFORMATION:**Table of Contents**

- I. Introduction
- II. NPL Deletion Criteria
- III. Deletion Procedures
- IV. Basis of Intended Site Deletion

I. Introduction

The Environmental Protection Agency (EPA), Region 10 announces its intent to delete a site from the National Priorities List (NPL), Appendix B of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), 40 CFR part 300, and requests comments to this deletion. EPA identifies sites on the NPL that appear to present a significant risk to human health or the environment. As described in section 300.425(e)(3) of the NCP, sites deleted from the NPL remain eligible for Fund-financed remedial actions in the unlikely event that conditions at the site warrant such actions.

EPA plans to delete the Northwest Transformer South Harkness Street Site ("Site") at 107 South Harkness Street, Everson Washington, from the NPL.

EPA will accept comments on the plan to delete this Site for thirty days after publication of this document in the **Federal Register**.

Section II of this document explains the criteria for deleting sites from the NPL. Section III discusses procedures that EPA is using for this action. Section IV discusses the South Harkness Street Site and explains how the Site meets deletion criteria.

II. NPL Deletion Criteria

Section 300.425 (e) of the NCP provides that "releases" (sites) may be deleted from, or recategorized on, the NPL where no further response is appropriate. In making a determination to delete a site from the NPL, EPA shall consider, in consultation with the state, whether any of the following criteria have been met:

(i) Responsible parties or other parties have implemented all appropriate response actions required;

(ii) All appropriate Fund-financed responses under CERCLA have been implemented, and no further action by responsible parties is appropriate, or

(iii) The remedial investigation has shown that the release poses no significant threat to public health or the environment and, therefore, taking of remedial measures is not appropriate.

Even if a site is deleted from the NPL, where hazardous substances, pollutants or contaminants remain at the site *above* levels that allow for unlimited use and unrestricted exposure, EPA's policy is that a subsequent review of the site will be conducted at least every five years after the initiation of the remedial action at the site to ensure that the site remains protective of public health and the environment. In the case of the South Harkness Street Site, some hazardous substances were left on-site, therefore, the five-year review requirement of section 121(c) of SARA remains applicable. If new information becomes available that indicates a need for further action, EPA may require remedial actions. Whenever there is a significant release from a site deleted from the NPL, the site may be restored to the NPL without the application of the Hazard Ranking System.

III. Deletion Procedures

The following procedures were used for the intended deletion of this Site: (1) The September 29, 1994 ROD included language that documented the achievement of cleanup goals and the fact that no separate close out report was necessary; (2) The Washington Department Of Ecology (Ecology) has concurred with the proposed deletion decision; (3) A notice has been published in the local newspaper and has been distributed to appropriate Federal, State, and local officials and other interested parties announcing the commencement of a 30-day public comment period on EPA's Notice of Intent to Delete; and, (4) All relevant documents have been made available for public review in the Site information repositories.

Deletion of the Site from the NPL does not itself, create, alter or revoke any

individual rights or obligations. The NPL is designed primarily for information purposes to assist EPA management. As mentioned in Section II of this Notice, 40 CFR 300.425(e)(3) states that deletion of a site from the NPL does not preclude eligibility for future Fund-financed response actions.

EPA's Regional Office will accept and evaluate public comments on EPA's Notice of Intent to Delete before making a final decision. The Agency will prepare a Responsiveness Summary if any significant public comments are received.

A deletion occurs when the Regional Administrator places a final notice in the **Federal Register**. Generally, the NPL will reflect deletions in the final update following the Notice. Public notices and copies of the Responsiveness Summary will be made available to local residents by EPA's Regional Office in Seattle, Washington.

IV. Basis for Intended Site Deletion

The following Site summary provides the Agency's rationale for the intention to delete this Site from the NPL.

A. Site Background

The South Harkness Superfund Site was a former transformer manufacturing, service and reclamation facility located in a commercial/residential area of downtown Everson, Washington. The site is located in downtown Everson and is bordered by a City Park, Main Street businesses, and South Harkness Street. An alley runs through the site.

The 1-acre facility was operated by the NW Transformer Service Company from 1958 until 1987. The Company used a building on-site to manufacture, recycle and rebuild transformers and an unpaved lot for storage of transformers, drums, bulk materials and salvage. The Company transferred its main storage and salvage operations from its Mission and Pole Roads salvage yard, which is also on the NPL, to the South Harkness Street site in 1985. An Ecology inspection in 1985 detected high levels of polychlorinated biphenyls (PCBs) in on-site soils.

The facility was added to the NPL in 1990 due to PCB and metals contamination in the building and soils. No site-related groundwater contamination has ever been detected and there are no drinking water wells down gradient from the site.

B. History

The following is a brief summary of the site investigation, removal action, recent sampling results, and current conditions:

- Since the site is small and contaminant levels relatively low, it was addressed with a streamlined approach. The Potentially Responsible Parties (PRPs) agreed on 6/17/92 to perform the necessary Remedial Investigation/Feasibility Study and a removal action if necessary.

- Field Investigations started in January 1993. No contaminants of concern were found in groundwater at the site. The primary contaminants of concern were PCBs (up to 89 ppm in soils and structural materials) and Total Petroleum Hydrocarbons (TPH) up to 63,000 ppm in underlying soils.

- The possibility of significant contamination of the Nooksack River and sediments was determined to be unlikely. The air pathway was also ruled out as a pathway of significant concern.

- After review of an Engineering Evaluation and Cost Analysis of removal alternatives, EPA issued a proposed plan for a removal to eliminate the risk of the building collapsing, to provide additional data for the RI and risk assessment, and to remediate the site in accordance with remedial requirements if possible.

- The removal was performed between November 1993 and June 1994. The site now consists of two modified asphalt parking lots and an alley covering about four feet of clean soil. In most locations PCB concentrations are less than 1 ppm. Two locations show evidence of low-level PCB contaminations at depth beneath the clean soil and asphalt cap (7 ppm at 6 feet below the ground surface and 28 ppm at 12.5 feet).

- TPH is also present in soils beneath the cap/parking lots, at levels up to 24,000 ppm. In accordance with additional State requirements documented in the CERCLA No Further Action ROD, the owners of the affected properties have recorded notices on their deeds acknowledging the presence of contamination and their duty, and that of subsequent property owners, to sample soils if the cap is disturbed and if soils are found to be contaminated, to dispose of them in accordance with State and Federal Law.

- In four years of ground water sampling no detectable quantities of PCBs or TPH have been found. Data from three rounds of groundwater sampling prior to the Removal Action show that no chemicals of concern were detected in site groundwater samples above maximum contaminant levels for drinking. Post-RA groundwater sampling for Site-related contaminants (PCBs and TPH) was conducted in November 1994, March 1995, July 1995,

October 1995, and October 1996. No chemical compounds of concern related to the site were detected in these groundwater samples.

- EPA oversight sampling since the Removal Action has identified the presence of Pentachlorophenol in some groundwater samples, however no evidence of Pentachlorophenol was ever identified at the site during site inspections, field investigations, the Removal Action, or post-removal confirmation sampling. EPA has provided Ecology with these results and the Agencies have agreed that EPA will continue efforts to identify the source and potential impacts of the Pentachlorophenol, but that since there is no evidence to date that the Pentachlorophenol is site-related, its detection should not preclude deletion of this site from the NPL. Note that deleted sites remain eligible for future Fund-financed response actions should future conditions warrant such action, and whenever there is a significant release from a site or portion of a site deleted from the NPL, the site or portion may be restored to the NPL without application of the Hazard Ranking System.

- EPA sees no reason to require continued annual ground water monitoring for PCBs, although periodic monitoring to support five-year reviews may still be appropriate. TPH is being addressed as an additional state requirement, which the Washington Department of Ecology will determine whether or not to continue.

C. Characterization of Risk

- The risk assessment was done subsequent to the Removal Action, and documented that current and future potential risks posed by the site are within the acceptable risk range of 10⁻⁵ or less. There is no current pathway for human exposure since all soil contamination has been removed and/or capped and no site-related contaminants of concern have been detected in groundwater. Because site risks were so low, EPA determined that no feasibility study was necessary and no other alternatives were considered or evaluated.

- The site remains a useful parking lot, serving downtown Everson, including the Senior Center and City Hall.

D. Public Participation

Community input has been sought by EPA Region 10 throughout the cleanup process at the Site. An information repository was established and has been maintained at the Everson Public Library. Fact sheets and public notices

were distributed when the site was placed on the NPL in 1990, when Notice Letters were sent to the PRPs in December 1991, when the Removal Action was proposed in August 1993, and at several other times.

A public comment period was held from August 16 to September 15, 1993 on the proposed removal action. At that time the public was informed that if the Removal Action was successful, no further action would likely be necessary. EPA issued a Proposed Plan calling for No Further Action on August 24, 1994, and held a public comment period from August 26 to September 26, 1994. A fact sheet and two public notices of the Plan were issued by EPA, but EPA received no public comments on the Proposed Plan.

A copy of the Deletion Docket can be reviewed by the public at the Everson Public Library, or the EPA Region 10 Superfund Records Center. The Deletion Docket includes this Notice, the ROD, Amended ROD, Remedial Action Construction Report, and Final Site Close-Out Report. EPA Region 10 will also announce the availability of the Deletion Docket for public review in a local newspaper and informational fact sheet.

One of the three criteria for deletion specifies that EPA may delete a site from the NPL if "responsible parties or other persons have implemented all appropriate response actions required." EPA, with the concurrence of Ecology, believes that this criterion for deletion has been met. Groundwater and soil data from the Site confirm that the ROD cleanup goals have been achieved. There is no significant threat to human health or the environment and, therefore, no further remedial action is necessary. Consequently, EPA is proposing deletion of this Site from the NPL. Documents supporting this action are available in the docket at the information repositories.

Dated: August 4, 1997.

Randall F. Smith,

Acting Regional Administrator.

[FR Doc. 97-21380 Filed 8-14-97; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CC Docket No. 96-128]

Pleading Cycle Established For Comment On Remand Issues In The Payphone Proceeding

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document clarifies the status of the requirements in the *Payphone Orders* in light of the D.C. Circuit's decision in *Illinois Public Telecomm.*, and establishes a pleading cycle for comment on issues remanded by that Court.

DATES: Comments are due on or before August 26, 1997 and reply comments are due on or before September 9, 1997.

ADDRESSES: Office of the Secretary, Federal Communications Commission, Room 222, 1919 M St. N.W., Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Greg Lipscomb, Formal Complaints and Information Branch, Enforcement Division, Common Carrier Bureau. (202) 418-0960.

SUPPLEMENTARY INFORMATION: DA 97-1673, August 5, 1997.

Comments Due: August 26, 1997.

Reply Comments Due: September 9, 1997.

I. Introduction

1. This Public Notice clarifies the status of the requirements of the *Payphone Orders*¹ in light of the D.C. Circuit's decision in *Illinois Public Telecommunications Ass'n v. FCC*,² and seeks further comment on certain issues raised by that court decision. In *Illinois Public Telecomm.*, the court granted in part and denied in part petitions for judicial review of the *Payphone Orders*. In doing so, however, the court actually vacated only one narrow aspect of those orders, *i.e.*, the asset valuation standard that the Commission adopted with respect to transfers of telephone company payphone assets to separate affiliates. The remaining portions of the orders were either upheld, or remanded to the Commission for further consideration and explanation. Thus,

¹Implementation of the Pay Telephone Reclassification and Compensation Provisions of the Telecommunications Act of 1996, CC Docket No. 96-128, Report and Order, 11 FCC Rcd 20541 (1996) ("Payphone Order"); Order on Reconsideration, 11 FCC Rcd 21233 (1996) ("Order on Reconsideration") (both orders together "Payphone Orders"); 61 Fed. Reg. 65,341 (Dec. 12, 1996).

²D.C. Circuit Nos. 96-1394 *et al.* (July 1, 1997).

except for the vacated asset valuation standard, all of the requirements of the *Payphone Orders*—including those portions that were remanded to the Commission—remain in effect pending further action by the Commission on remand.³ We place the industry on notice, however, that should the equities so dictate, payphone compensation payment obligations (or the absence of such obligations) incurred by providers of interexchange services and compensation levels paid or received under our existing rules pending action on remand may be subject to retroactive adjustment in order to undo the effects of applying aspects of the current rules that were identified by the court as potentially arbitrary.⁴

2. As discussed below, we also seek comment to supplement the record on certain issues raised by the court's ruling in *Illinois Public Telecomm.*

II. Issues for Comment

A. Default Rate for Compensation of Subscriber 800 and Access Code Calls

3. The court concluded that the Commission did not adequately justify setting the per-call compensation rate for subscriber 800 and access code calls at the same rate as the deregulated local call rate of \$.35. In particular, the court held that the Commission did not justify its conclusion that the costs of coin calls, subscriber 800 calls, and access code calls all are similar.⁵ The court concluded that the Commission had not responded to arguments by parties in the proceeding that the "costs of local coin calls versus 800 and access code calls are not similar." The court cited the filings of various IXC's that argued that: (1) the costs of coin calls are higher than those for coinless calls because of additional costs for equipment and coin collection; (2) the costs of local coin calls are higher because the PSP pays for originating and completing local calls

while, for coinless calls (e.g., subscriber 800 calls or access code calls) the PSP only pays for originating the calls.⁶

4. We seek comment on the differences in costs to the PSP of originating subscriber 800 calls and access code calls, on the one hand, and local coin calls, on the other hand. We also seek comment on whether and, if so, how these cost differences should affect a market-based compensation amount. Finally, we seek comment on whether the local coin rate, subject to an offset for expenses unique to those calls, is an appropriate per-call compensation rate for calls not compensated pursuant to a contract or other arrangement, such as subscriber 800 calls and access code calls. Parties should respond specifically to concerns raised by the court in setting forth their views on the appropriate per-call compensation amount.

B. Interim Compensation Plan

5. In the *Payphone Orders*, the Commission established a two-year interim plan for payphone compensation for subscriber 800 and access code calls based on a rate of \$.35 per call. Under the first year of the interim plan, IXC's with annual toll revenues in excess of \$100 million are required to pay, collectively, a flat-rate compensation of \$45.85 per payphone per month in shares proportionate to their share of total market long distance revenues. During the second year, all IXC's are required to pay \$.35 per subscriber 800 call or access code call unless they have contracted for a different amount.

6. The court remanded the interim plan for two reasons. First, the court concluded that the Commission failed to provide a reasonable justification for an interim rate based on \$.35 per call. As discussed above, the court remanded the decision to set compensation for subscriber 800 calls and access code calls at the deregulated local coin rate. The court concluded that the Commission "must now set a new interim rate and decide what is to happen once the interim period is over."⁷ Second, the court held that the Commission acted arbitrarily and capriciously because it required payments only from IXC's with over \$100 million in toll revenues for the first year of the interim plan. The court concluded that administrative convenience was an insufficient justification for an interim plan that exempts all but large IXC's from paying

for the costs of services received.⁸ In addition, the court found that the Commission did not adequately justify why it based its interim plan on total toll revenues, "as it did not establish a nexus between total toll revenues and the number of payphone-originated calls." The court concluded that the Commission could decide that the new interim rate is an appropriate default rate after the interim period and that, through negotiations, PSP's and IXC's could be left free to depart from the default rate.⁹

i. Compensation for Subscriber 800 and Access Code Calls During the Interim Period

7. In response to the court's conclusion that the Commission had not justified setting the interim flat rate compensation level on the basis of \$.35 per call (which we had multiplied by an estimate of the number of monthly compensable calls), we seek comment on the proper aggregate amount of compensation PSP's should receive per payphone during the period before per call compensation becomes available.

8. We also seek comment on the proper allocation of a flat-rate compensation obligation, if any, among providers of interexchange service. The Commission currently does not have specific toll revenue data or market share data for IXC's with toll revenues under \$100 million. Consequently, we seek comment on how the Commission could establish the relative compensation obligations of such smaller IXC's, if such carriers were to be included in the interim compensation mechanism. We also seek comment on whether annual toll revenues are the appropriate basis for allocating flat-rate compensation obligations among all of the IXC's, regardless of their annual toll revenues, or whether some other basis is more appropriate. If parties argue that another basis is appropriate for allocating flat-rate compensation, they should also discuss how differences in the amount of interim compensation obligations would be accounted for, given that the existing interim mechanism continues to be in effect. We also seek comment on whether the Commission should include LEC's that carry toll traffic among the carriers required to pay interim compensation, and, if so, the data we would use to ascertain their respective obligations.¹⁰

⁸ *Id.*

⁹ *Id.*

¹⁰ LEC's are currently excluded from interim obligations because of "... administrative practicality and because LEC's, on an individual basis, currently do not carry a significant volume

³ See *Allied-Signal Inc. v. NRC*, 988 F.2d 146, 151 (D.C. Cir. 1993); *Checkosky v. SEC*, 23 F.3d 452, 463 (D.C. Cir. 1994) (opinion of Silberman, J.). It follows logically that because the court held that the failure of the Commission to provide interim compensation for 0+ calls that are not compensated pursuant to contract is arbitrary and capricious and not responsive to the § 276 requirement that there be compensation for each and every call, the court would similarly find a decision by the Commission to discontinue interim compensation during the remand proceedings as contrary to § 276. The court's decision to remand but not vacate the interim compensation provisions of the *Payphone Orders* supports this assumption.

⁴ See *Natural Gas Clearinghouse v. FERC*, 965 F.2d 1066, 1073-75 (D.C. Cir. 1992); *Public Utils. Comm'n of California v. FERC*, 988 F.2d 154, 162-63 (D.C. Cir. 1993).

⁵ *Illinois Public Telecomm.*, No. 96-1394, slip op. at 16.

⁶ *Id.* at 14.

⁷ *Id.* at 17.

ii. Compensation for 0+ Calls During the Interim Period

9. The *Payphone Orders* do not provide compensation for any calls that are compensated pursuant to a contract between the PSP and a presubscribed carrier. The interim compensation mechanism provides compensation only for subscriber 800 calls and access code calls,¹¹ which are the most significant classes of calls currently not compensated pursuant to contract. The court found that the Commission's "failure to provide interim compensation for 0+ calls is patently inconsistent with § 276's command that fair compensation be provided for 'each and every completed . . . call.'"¹² As the Commission noted in the *Payphone Order*, a significant number of payphones maintained by the BOCs are not subject to a contract between the PSP and the presubscribed IXC, due to the previous restrictions imposed by the Modification of Final Judgment.¹³ Because the court's statement is made in response to an argument made by the BOCs, it appears that the court's concern about a lack of compensation for 0+ calls in the interim period is limited to situations where such compensation is not paid pursuant to a contract. We seek comment on this interpretation. Further, we seek comment on how the BOCs, and any other similarly situated PSP, should be compensated during the interim period for 0+ calls for which they do not receive compensation by contract. More specifically, because the presubscribed carrier on a particular payphone receives the 0+ calls from that payphone and often pays a commission on such calls to the location provider, we seek comment on whether it would be appropriate to have the presubscribed carrier pay the default per-call compensation amount to the PSP for each such call. The concerns that the Commission expressed when it deferred per-call tracking and per-call compensation are not implicated in this

of compensable calls." *Order on Reconsideration*, 11 FCC Rcd at 21291, para. 126.

¹¹ *Payphone Order*, 11 FCC Rcd at 20603-04, paras. 124-25.

¹² *Illinois Public Telecomm.*, No. 96-1394, slip op. at 19.

¹³ See *United States v. Western Elec. Co.*, 698 F. Supp. 348, 360 (D.D.C. 1988) (*MFJ*). The BOCs were not compensated for these calls through contracts with IXCs like other PSPs. The Commission included per-call compensation for 0+ plus calls made from BOC payphones and inmate payphones so long as they do not otherwise receive compensation for originating 0+ calls. The Commission did not, however, provide for such compensation during the first year of the interim period. *Order on Reconsideration*, 11 FCC Rcd at 21259-60, para. 52.

situation, because the presubscribed carrier is already keeping track of these calls. The presubscribed carrier could simply pay the PSP for the number of calls it has received from the payphone multiplied by the default rate. We seek comment on this option, and any other options parties may suggest for responding to the court's concerns.

iii. Compensation for Inmate Calls During the Interim Period

10. In the *Payphone Orders*, the Commission decided that inmate payphones would not be eligible for interim flat-rate compensation because such payphones are not capable of originating either access code or subscriber 800 calls, the only types of calls for which interim compensation was provided.¹⁴ The Commission found that virtually all calls originated by inmate payphones are 0+ calls, which tend to be compensated pursuant to a contract between the PSP or location provider and the presubscribed IXC.¹⁵ The court remanded this issue because it held that § 276 requires the Commission to adopt regulations that will ensure that PSPs receive fair compensation for every call using their payphone as required by the Act.¹⁶ As with its discussion of interim compensation for 0+ calls, the court's statements were made in response to arguments made by the BOCs. Thus, as we discussed above, it appears that the court's concern about a lack of compensation for inmate calls in the interim period is limited to situations where such compensation is not paid pursuant to a contract. We seek comment on this interpretation. Further, we seek comment on how the BOCs, and any other similarly situated PSP, should be compensated for inmate payphone calls during the interim period. We specifically seek comment on whether it would be appropriate to have the presubscribed carrier pay the default per-call compensation amount to the PSP for each inmate payphone call for which compensation is not provided pursuant to a contract with the PSP. Again, the Commission's concerns absent tracking and per-call compensation are not implicated in this situation, because the presubscribed carrier is already keeping track of the calls.

¹⁴ *Order on Reconsideration*, 11 FCC Rcd at 21259-12160, para. 52.

¹⁵ *Id.*

¹⁶ *Illinois Public Telecomm.*, No. 96-1394, slip op. at 19-20.

iv. Retroactive Adjustments to Interim Compensation Levels and Obligations

11. As noted at the outset of the Public Notice, the Commission may impose retroactive adjustments to the payment obligations and compensation levels that are incurred under our existing rules during the period before the Commission completes action on remand. We seek comment on whether, how, and under what authority any such retroactive adjustments should be made. Parties should specify the time period covered by such potential adjustments, *e.g.*, the entire first year of interim compensation (beginning in October 1996), or from the date of the court's remand in *Illinois Public Telecomm. Ass'n*.

C. Asset Valuation

12. In order to implement the § 276 requirement to remove subsidies from payphone operations,¹⁷ the Commission required deregulation of payphone assets.¹⁸ Upon deregulation of payphone assets, LECs are allowed either to maintain the assets in their books of account but reclassify the assets as nonregulated, or to transfer the payphone assets to a structurally separate affiliate.¹⁹ In the *Payphone Order*, the Commission stated that LECs that elect not to transfer their payphone assets to a separate affiliate may maintain their assets on the books at net book value. The Commission further stated that, under its affiliate transactions rules, if a LEC transfers its payphone assets to either a separate affiliate or an operating division that has no joint and common use of assets or resources with the LEC and maintains a separate set of books, the LEC must record the transfer of assets at the higher of fair market value or net book value. The Commission concluded that fair market valuation will capture any appreciation in value of those assets, "thus ensuring that any eventual gains

¹⁷ Section 276(a)(1) provides that "any Bell operating company that provides payphone service shall not subsidize its payphone service directly or indirectly from its telephone exchange service operations or its exchange access operations." 47 U.S.C. 276(a)(1). Paragraph (b) of § 276 requires the Commission to issue "regulations that . . . discontinue . . . all intrastate and interstate payphone subsidies from basic exchange and exchange access revenues." *Id.* U.S.C. 276(b)(1)(B).

¹⁸ See *Payphone Order*, 11 FCC Rcd at 20,621, para. 142-45.

¹⁹ 47 CFR 32.27(b). See *Payphone Order*, 11 FCC Rcd at 20,621, para. 157. The court rejected the petitioners' argument that § 276 requires that a BOC's payphone assets be transferred to its unregulated books. *Illinois Public Telecomm.*, No. 96-1394, slip op. at 28.

would accrue to the benefit of the ratepayers and shareholders.”²⁰

14. The court held that the Commission’s valuation methodology with respect to the one-time transfer of assets mandated by industry reform was arbitrary and capricious and contrary to precedent.²¹ The court concluded that the Commission failed to recognize that the court’s test in *Democratic Central*, which the Commission declined to apply, was designed to protect not only the interests of ratepayers, but also the competing interests of shareholders.²² The court found inappropriate under *Democratic Central* the Commission’s valuation methodology, because the court held that the Commission was attempting to transfer the increase in the value of the payphone operations from the LECs’ shareholders to ratepayers. The court held that, under *Democratic Central*, as a result of the Commission’s price cap rules, investors rather than ratepayers have borne the risk of loss on payphone assets. Therefore, the court concluded that investors should reap the benefit of increases in the value of such assets.²³ The court stated that in *Southwestern Bell Corp. v. FCC*, while upholding the Commission’s affiliate transactions rules, specifically “noted *Democratic Central*’s continued applicability to ‘one-time’ transfers mandated by industry reform.” The court held that the transfer of payphone assets pursuant to § 276 fell within this category.²⁴ The court rejected upon similar analysis a challenge by other petitioners to the net book valuation method required by the Commission with respect to the reclassification of payphone assets as nonregulated within the same corporate entity.²⁵

15. We seek comment on how the asset valuation requirements for the transfer of payphone assets established in the *Payphone Orders* should be revised to respond to the concerns raised by the court. The court appears to hold that net book value must be used for one-time transfers mandated by industry reform, which would apply to payphone asset transfers. If other approaches are recommended, parties should address how such approaches

comply with the court’s *Democratic Central* analysis.

III. Ex Parte Presentations

16. This Public Notice is a “permit-but-disclose proceeding and subject to the “permit-but-disclose” requirements under § 1.1206(b) of the rules, 47 CFR 1.1206(b), as revised. Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must contain a summary of the substance of the presentation and not merely a listing of the subjects discussed. More than a one or two sentence description of the views and arguments presented is generally required. See 47 CFR 1.1206(b)(2), as revised. Other rules pertaining to oral and written presentations are set forth in § 1.1206(b), as well. The Commission requires all written *ex parte* presentations or summaries of oral *ex parte* presentations in this proceeding to be served on all parties to this proceeding.

IV. Comment Filing Dates

17. Pursuant to applicable procedures set forth in §§ 1.415 and 1.419 of the Commission’s rules, 47 CFR 1.415, 1.419, interested parties may file comments with the Office of the Secretary, Federal Communications Commission, Room 222, 1919 M St., N.W., Washington, D.C. 20554 on or before August 26, 1997, and reply comments on or before September 9, 1997 from the release of this public notice. To file formally in this proceeding, participants must file an original and four copies of all comments, reply comments, and supporting comments. In addition, parties should file two copies of any such pleadings with the Chief, Enforcement Division, Common Carrier Bureau, Stop 1600A, Room 6008, 2025 M Street, N.W., Washington, D.C. 20554. Parties should also file one copy of any documents filed in this docket with the Commission’s copy contractor, International Transcription Services, Inc., 1231 20th Street, N.W., Washington, D.C. 20036. Comments and reply comments will be available for public inspection during regular business hours in the FCC Reference Center (Room 239), 1919 M Street, N.W., Washington, D.C.

17. For further information, contact Michael Carowitz, Rose Crellin, or Greg Lipscomb, Enforcement Division, Common Carrier Bureau, 202/418–0960.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 97–21819 Filed 8–14–97; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[I.D. 080597F]

RIN: 0648–AK14

Amendment 34 to the Fishery Management Plan for the Groundfish Fishery in the Bering Sea and Aleutian Islands Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce

ACTION: Notice of availability of an amendment to a fishery management plan; request for comments.

SUMMARY: The North Pacific Fishery Management Council (Council) has submitted Amendment 34 to the Fishery Management Plan for the Groundfish Fishery in the Bering Sea and Aleutian Islands Area (FMP) for Secretarial review. Amendment 34 would authorize an allocation of Atka mackerel to vessels using jig gear. Annually, up to 2 percent of the total allowable catch (TAC) specified for this species in the Eastern Aleutian Islands District (AI)/Bering Sea subarea (BS) could be allocated to the jig gear fleet fishing in this area. This action is necessary to provide an opportunity to a localized, small-vessel jig gear fleet to fish for Atka mackerel in summer months. The large-scale trawl fisheries typically harvest the available TAC for this species early in the fishing year, which does not allow the jig gear fishermen an opportunity for a summer fishery. Comments from the public are requested.

DATES: Comments on Amendment 34 must be submitted on or before October 14, 1997.

ADDRESSES: Comments on Amendment 34 should be submitted to Chief, Fisheries Management Division, Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802-1668, Attn: Lori Gravel, or delivered to the Federal Building, 709 West 9th. Street, Juneau, AK. Copies of Amendment 34 and the Environmental Assessment/Regulatory Impact Review/Initial Regulatory Flexibility Analysis prepared for the amendment are available from NMFS at the above

²⁰ *Payphone Order*, 11 FCC Rcd at 20,623–20,625, paras. 163–66.

²¹ *Illinois Public Telecomm.*, No. 96–1394, slip op. at 28.

²² *Id.* at 26, citing *Democratic Cent. Comm. of the Dist. of Columbia v. Washington Metro. Area Transit Comm’n*, 485 F.2d 785, 806 (D.C. Cir. 1973), cert. denied, 415 U.S. 935 (1974) (*Democratic Central*).

²³ *Id.* at 27.

²⁴ *Id.* (citing *Southwestern Bell Corp. v. FCC*, 896 F.2d 1378, 1382 (D.C. Cir. 1990)).

²⁵ *Illinois Public Telecomm.*, No. 96–1394, slip op. at 28.

address, or by calling the Alaska Region, NMFS at 907-586-7228.

FOR FURTHER INFORMATION CONTACT: Susan Salveson, 907-586-7228.

SUPPLEMENTARY INFORMATION: The Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) requires that each Regional Fishery Management Council submit any fishery management plan (FMP) or plan amendment it prepares to NMFS for review and approval, disapproval, or partial approval. The Magnuson-Stevens Act also requires that NMFS, upon receiving an FMP or amendment, immediately publish a document that the FMP or amendment is available for public review and comment. NMFS will consider the public comments received during the comment period in

determining whether to approve the FMP or amendment.

Amendment 34 was adopted by the North Pacific Fishery Management Council at its June 1997 meeting and would authorize an allocation of Atka mackerel to vessels using jig gear. Annually, up to 2 percent of the annual TAC specified for Atka mackerel in the Eastern AI/BS could be allocated to vessels using jig gear as part of the annual groundfish specifications process. The percent allocation, up to the 2 percent ceiling, would be based on recent and anticipated harvest capacity of the jig gear fleet. This amendment is being proposed to respond to concerns that the developing small vessel jig gear fishery for Atka mackerel during spring and summer months routinely is precluded by the fast-paced trawl

fisheries for this species that typically harvest the available TAC in the Eastern AI/BS early in the fishing year.

NMFS will consider the public comments received during the comment period in determining whether to approve the proposed amendment. A proposed rule to implement Amendment 34 has been submitted for Secretarial review and approval. The proposed rule to implement this amendment is scheduled to be published within 15 days of this document.

Dated: August 11, 1997.

Gary C. Matlock,

*Director, Office of Sustainable Fisheries,
National Marine Fisheries Service.*

[FR Doc. 97-21596 Filed 8-14-97; 8:45 am]

BILLING CODE 3510-22-F

Notices

Federal Register

Vol. 62, No. 158

Friday, August 15, 1997

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.

HARRY S. TRUMAN SCHOLARSHIP FOUNDATION

Sunshine Act Meeting; Annual Meeting of the Trustees and Officers of the Harry S. Truman Scholarship Foundation

4:00–5:30 p.m., September 24, 1997, Room HC 6, The United States Capitol

1. Call to Order and Welcome, Vice Chairman Skelton
2. Introduction of Trustees attending their first Annual Meeting
3. Approval of the Minutes of the 1996 Annual Meeting
4. Proposal for a partnership with a consortium of institutions to increase participation of Historically Black Colleges and Universities in the Truman Scholarship program
5. Proposal to fund an experimental Truman Scholars Alumni Program for 1997–98
6. Proposal to provide one-week Truman Scholar internships with Foundation Trustees
7. Foundation participation in the commissioning ceremony of the USS Harry S. Truman
8. Introduction of Truman Scholars working in the Washington area
9. Executive Secretary's Report including
 - Leadership at the Foundation
 - Expenditures for FY 1997
 - Status of the Trust Fund
 - Overview of the 1997 Truman Scholars Selection
 - Plans for the 1998 Truman competition
 - Truman Foundation Honor Institution awards
 - Report on the workshop Success with the Truman
10. Proposal to commission an audit of the Fiscal Year 1997 operations of the Foundation
11. New Business

12. Adjournment

[FR Doc. 97–21846 Filed 8–13–97; 3:57 pm]

BILLING CODE 4738–10–M

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Committee of Scientists

AGENCY: Office of the Secretary, USDA.

ACTION: Notice; establishment and request for nominations.

SUMMARY: The Secretary of Agriculture is establishing a Committee of Scientists, under the Federal Advisory Committee Act, 5 U.S.C. App., to provide scientific and technical advice on improvements to the National Forest System land and resource management planning process. The Committee's report is due to the Secretary of Agriculture and the Chief of the Forest Service 4 months from its initial meeting, unless additional time is needed. Nominations of persons to serve on the Committee of Scientists are invited.

DATES: Nominations for membership on the Committee of Scientists must be received in writing by September 2, 1997.

ADDRESSES: Nominations for membership on the Committee of Scientists may be sent via telefax to the Director, Ecosystem Management Coordination at (202) 205–1012 or via mail to the Director, Ecosystem Management Coordination, MAIL STOP 1104, Forest Service, P.O. Box 96090, Washington, DC 20090–6090.

FOR FURTHER INFORMATION CONTACT: Jonathan Stephens, Ecosystem Management Coordination Staff, Forest Service, telephone: (202) 205–0948.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act (5 U.S.C. App.), notice is hereby given that the Secretary of Agriculture intends to establish a Committee of Scientists. The purpose of the Committee of Scientists is to provide scientific and technical advice to the Secretary of Agriculture and the Chief of the Forest Service on improvements that can be made to the land and resource management planning process. The Committee will address such topics as how to consider the following in land and resource management plans:

biological diversity, use of ecosystem assessments in planning, spatial and temporal scales for planning, public participation processes, sustainable forestry, interdisciplinary analysis, and any other issues the Committee identifies as relevant to land and resource management planning.

The Committee of Scientists shall prepare a report and make recommendations to the Secretary and the Chief of the Forest Service on how best to accomplish sound resource management planning within the established framework of environmental laws and within the statutory mission of the Forest Service. The Committee's report shall be made available to the public. The Committee of Scientists shall also provide technical advice on the land and resource management planning process and provide material for the Forest Service to consider for incorporation into the revised planning regulations. The Committee shall also recommend improvements in Forest Service coordination with other Federal land management agencies or resource protection agencies, State and local government agencies, and tribal governments, in order to recognize the unique roles and responsibilities of each agency in the planning process.

The Secretary has determined that the work of the Committee is in the public interest and relevant to the duties of the Department of Agriculture.

The Committee of Scientists shall consist of no more than 12 members and a Committee chair appointed by the Secretary of Agriculture. Officers or employees of the Forest Service may not serve as members of the Committee. The Committee of Scientists shall be composed of representatives who can prove insights into the major contemporary issues associated with the National Forest Management Act and its implementation. Members should represent scientific specialties and academic disciplines including, but not limited to, the following fields: forest and range ecology, fish and wildlife biology, silviculture, hydrology, natural resource economics, sociology, public participation and conflict management, ecosystem management, land management planning, and natural resource law. Collectively, the members should represent a diversity of disciplines and perspectives, have a knowledge of the National Forest

System, the National Forest Management Act, and the National Forest planning process. Nominations to the Committee should describe and document the proposed member's qualifications for membership on the Committee of Scientists.

Appointments to the Committee will be made by the Secretary of Agriculture. Equal opportunity practices will be followed in all appointments to the Committee of Scientists. To ensure that the recommendations of the Committee have taken into account the needs of the diverse groups served by the Department, membership will include, to the extent practicable, individuals with demonstrated ability to represent minorities, women, and persons with disabilities.

Dated: July 18, 1997.

Christine Pytel,

Acting Deputy Assistant Secretary for Administration.

[FR Doc. 97-21725 Filed 8-14-97; 8:45 am]

BILLING CODE 3410-11-M

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 97-048N]

Technical Meeting to Solicit Input for a Survey on Browning in Hamburger

AGENCY: Food Safety and Inspection Service.

ACTION: Notice.

SUMMARY: The Food Safety and Inspection Service (FSIS) is holding a public technical meeting on August 20, 1997. The purpose of the meeting is to solicit scientific information, including data, on a proposed survey to determine the frequency with which hamburger, sold at retail and cooked at home, turns brown before reaching 160 degrees F. The results of this survey will be used to determine the contribution of this factor to a risk assessment for *E. coli* O157:H7. Persons with an interest in the study, particularly in details such as sampling, preparation, cooking, and evaluation procedures to be used in this survey, are especially encouraged to attend.

DATES: The meeting will be held on August 20, 1997, from 8:30 a.m. to 1:00 p.m. Registration will begin at 8:00 a.m., and materials will be available at that time.

ADDRESSES: The half-day meeting will be held at the Washington Plaza Hotel, 10 Thomas Circle, at Massachusetts Avenue and 14th Street, Washington, DC 20008.

FOR FURTHER INFORMATION CONTACT: To register for the meeting, contact Ms. Traci Phebus at (202) 501-7138 or FAX (202) 501-7642. To arrange for presentation of technical materials, contact Mr. David Soderberg at (202) 501-7358 or FAX (202) 501-7639. Presenters are asked to submit one original and two copies of written comments to the FSIS Docket Clerk, Docket #97-048N, Department of Agriculture, FSIS, 102 Cotton Annex, 300 12th Street, Washington, DC 20250-3700. Persons wishing to present technical data are asked to bring 100 copies of their data for distribution to participants in the meeting. Participants who require a sign language or other special accommodations should contact Ms. Phebus at the above numbers by August 13, 1997.

SUPPLEMENTARY INFORMATION: A pilot study to prepare for this survey was undertaken. Preliminary results from the pilot study may be available for this meeting, but the primary purpose of the pilot study was to try out laboratory techniques (for example, cooking and color evaluation) and to test logistics before initiating the main survey. Actual results from the pilot study may require more confirmation before they can be determined to be scientifically accurate. It is expected that discussions in the August 20 meeting will focus on technical details of the proposed survey. Sampling may be a major topic of discussion. The purpose of this meeting is to solicit advice on the survey design from consumers, public health officials and others.

Persons with expert knowledge about consumer behavior in the purchasing, preparing, and cooking of hamburger are especially encouraged to attend. Persons unable to attend the meeting may submit comments to the above addresses.

Transcripts of this meeting will be available in the FSIS Docket Room.

Done at Washington, DC, on: August 7, 1997.

Thomas J. Billy,

Administrator.

[FR Doc. 97-21673 Filed 8-14-97; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF AGRICULTURE

Forest Service

Supplement to the Draft Environmental Impact Statement for ASARCO's Rock Creek Project, Copper/Silver Mine, Kootenai National Forest, Sanders County, MT

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare a supplement to the draft environmental impact statement.

SUMMARY: The USDA Forest Service, Kootenai National Forest (KNF) in conjunction with Montana Department of Environmental Quality (DEQ) will prepare a Supplement to the Draft Environmental Impact Statement (SDEIS) for ASARCO's proposal to develop the Rock Creek copper/silver mine project approximately 5 miles northeast of Noxon, Montana.

The original notice of intent was published in the **Federal Register**, Volume 53, No. 9, January 14, 1988. A number of items including lead agency, mine water disposal, release date of the SDEIS have changed since 1988. This revised notice describes the current situation.

The KNF and DEQ are joint lead agencies in this effort. Joint lead status will allow both agencies to fulfill their interrelated responsibilities in managing the process for preparation of the draft, supplement and final EIS documents under the guidelines of the National Environmental Policy Act and the Montana Environmental Policy Act, respectively. The DEQ administers the 1971 Montana Metal Mine Reclamation Act. The purposes of the act are, first, to recognize and protect the usefulness, productivity, and scenic values of the lands and waters within the state and second, to reclaim to beneficial use the lands used for metal mines. The Forest Service has the responsibility for managing the uses of the Federal surface land and resources.

This SDEIS is being prepared because there is new information relevant to environmental concerns about the proposed action (40 CFR part 1502.9(c)(1) (i & ii)). The revised notice of intent to prepare the draft environmental impact statement (DEIS) was published in the May 27, 1993, **Federal Register** (Vol. 58, No. 101). The notice of availability for the ASARCO Rock Creek Copper and Silver Mining Project DEIS was published in the October 6, 1995, **Federal Register** (Vol. 60, No. 194).

The public comment received on the DEIS has lead the Agencies to take a look at revising some proposed portions of the operation. A new alternative (Alt. V) has been developed which includes the surface deposition of tailings as a paste, and a water treatment system using a semi-passive bioreactor and a reverse osmosis process. The concentrate from the mill would be pumped to an enclosed rail loadout facility. There are also changes in mitigations for the project which

include change in: the type of diesel engines used, the type of pipe used to transport materials and the depth buried, the use of seepage collection features, the design intensity for storm diversions and ponds, the busing of employees, the closing of roads and additional monitoring.

The public will be informed of the availability of the SDEIS by a notice of availability in the **Federal Register**, news releases and mailings of those on the mailing list. The anticipated date of release of the SDEIS for comment is Fall, 1997.

DATES: Specific comments concerning the scope of the analysis should be submitted by September 15, 1997.

ADDRESSES: The responsible official is Robert Schrenk, Forest Supervisor, Kootenai National Forest. Written comments and suggestions concerning the re-analysis and the proposed SDEIS should be sent to the responsible official at 506 U.S. Highway 2 West, Libby, MT 59923.

FOR FURTHER INFORMATION:

Paul Kaiser, Project Coordinator, Kootenai National Forest. Phone: (406) 293-6211.

SUPPLEMENTARY INFORMATION: A new alternative (V) was developed to address the new information received and concerns raised since release of the DEIS on October 6, 1995.

Original Proposed Action

ASARCO's proposal, which was submitted in 1987, includes constructing a 10,000 ton per day mine and mill complex to develop their stratiform copper/silver ore deposit which is located under the Cabinet Mountains Wilderness. The ore would be accessed via tunnels starting outside and downslope from the wilderness boundary. ASARCO estimates an ore reserve of 136 million tons and mine recovery rate of 65 percent. ASARCO projects the estimated mine life (from beginning through reclamation) to be 32 years. The mine is estimated to employ 305-355 people. Parts of the project would be on National Forest System land with the remainder on private land. Facilities would include a tailings impoundment approximately 250' high and 324 acres in size, a new access road, utility corridor, water lines, wells, mill site, water treatment site, and rail loadout facility. An exploration adit is proposed to further define the ore body. Two parallel adits (horizontal access passages) would be drilled, one would be used for the ore conveyor and the other for mine access. Two ventilation adits are proposed, one to have its surface opening within the wilderness

and the other would use the proposed exploration adit outside the wilderness. Excess mine water is proposed to be discharged to the Clark Fork River after being treated to State water quality standards.

New Alternative

The new alternative (Alt. V) proposal includes activities on approximately 483 acres. Alternative V has been developed which includes the surface deposition of tailings as a paste, and a water treatment system using a semi-passive bioreactor and a reverse osmosis process. The concentrate from the mill would be pumped to an enclosed rail loadout facility. There are also changes in mitigations for the project which include change in: the type of diesel engines used, the type of pipe used to transport materials and the depth buried, the use of seepage collection features, the design intensity for storm diversions and ponds, the busing of employees, the closing of roads and additional monitoring.

Reviewer Obligations

The Forest Service believes it is important to give reviewers notice at this early stage because of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the draft environmental impact statement stage but that are not raised until after completion of the final environmental impact statement may be waived or dismissed by the courts. *Wisconsin Heritages, Inc. v. Harris*, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day comment period so 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 environmental impact statement.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the supplement to the draft environmental impact statement should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the supplemental statement.

Comments may also address the adequacy of the supplemental to the draft environmental impact statement or the merits of the alternatives formulated and discussed in the statement. (Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.).

Dated: July 31, 1997.

Robert L. Schrenk,

Forest Supervisor, Kootenai National Forest.

[FR Doc. 97-20897 Filed 8-14-97; 8:45 am]

BILLING CODE 3410-11-M

DEPARTMENT OF AGRICULTURE

Forest Service

Cholmondeley Environmental Impact Statement

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an Environmental Impact Statement.

SUMMARY: The Department of Agriculture, Forest Service, will prepare an Environmental Impact Statement (EIS) to provide timber for the Ketchikan Area timber sale program. The Record of Decision will disclose how the Forest Service has decided to provide harvest units, roads, and associated timber harvesting facilities. The proposed action is to harvest up to an estimated 37 million board feet (mmbf) of timber on an estimated 1,700 acres. A range of alternatives will be developed and will include a no-action alternative. The proposed timber harvest is located within Tongass Forest Plan Management Areas K18 and K19, Value Comparison Units 614, 615, 616, 617, 674, 675 and 676 on Prince of Wales Island, Alaska, on the Craig Ranger District of the Ketchikan Area of the Tongass National Forest.

DATES: Comments concerning the scope of this project should be received by September 30, 1997.

ADDRESSES: Please send written comments to Forest Supervisor's Office; Tongass National Forest, Ketchikan Area; Attn: Cholmondeley EIS; Federal Building, Ketchikan, AK 99901.

FOR FURTHER INFORMATION CONTACT:

Questions about the proposal and EIS should be directed to Dale Kanen, District Ranger, Craig Ranger District, Tongass National Forest, P.O. Box 500, Craig, AK 99921 telephone (907) 826-3271 or Norm Matson, Planning Biologist, Federal Building, Ketchikan, AK 99901 telephone (907) 228-6273.

SUPPLEMENTARY INFORMATION: Public participation will be an integral component of the study process and will be especially important at several points during the analysis. The first is during the scoping process. The Forest Service will be seeking information, comments, and assistance from Federal, State, local agencies, individuals and organizations that may be interested in, or affected by, the proposed activities. The scoping process will include: (1) Identification of potential issues; (2) identification of issues to be analyzed in depth; and (3) elimination of insignificant issues or those which have been covered by a previous environmental review. Written scoping comments are being solicited through a scoping package that will be sent to the project mailing list. For the Forest Service to best use the scoping input, comments should be received by September 30, 1997. Tentative issues identified for analysis in the EIS include the potential effects of the project on and the relationship of the project to: Subsistence resources, old-growth ecosystem management and the maintenance of habitat for viable populations of wildlife and plant species, timber supply, scenery and recreational resources, anadromous and resident fish habitat, soil and water resources, wetlands, cultural resources and others.

Based on results of scoping and the resource capabilities within the project area, alternatives including a "no action" alternative will be developed for the Draft Environmental Impact Statement (Draft EIS). The Draft EIS is projected to be filed with the Environmental Protection Agency (EPA) in April 1998. Subsistence hearings, as provided for in Title VIII, Section 810 of the Alaska National Interest Lands Conservation Act (ANILCA), are planned during the comment period on the Draft EIS. The Final EIS is anticipated by April 1999.

The comment period on the draft environmental impact statement will be 45 days from the date the Environmental Protection Agency publishes the notice of availability in the **Federal Register**.

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp. v.*

NRDC, 435 U.S. 519, 553, (1978). Environmental objections that could have been raised at the draft environmental impact statement stage may be waived or dismissed by the courts. *City of Angoon v. Hodel*, 803 F.2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc. v. Harris*, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day comment period so 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 environmental impact statement.

To assist the Forest Service in identifying and considering issues and concerns of the proposed action, comments during scoping and comments on the draft environmental impact statement should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the draft environmental impact statement or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

Comments received in response to this solicitation, including names and addresses of those who comment, will be considered part of the public record on this proposed action and will be available for public inspection. Comments submitted anonymously will be accepted and considered; however, those who submit anonymous comments will not have standing to appeal the subsequent decision under 36 CFR Parts 215 or 217. Additionally, pursuant to 7 CFR 1.27(d), any person may request the agency to withhold a submission from the public record by showing how the Freedom of Information Act (FOIA) permits such confidentiality. Requesters should be aware that, under FOIA, confidentiality may be granted in only very limited circumstances, such as to protect trade secrets. The Forest Service will inform the requester of the agency's decision regarding the request for confidentiality, and where the request is denied, the agency will return the submission and notify the requester that the comments may be resubmitted with or without name and address within 7 days.

Permits: Permits required for implementation include the following:

1. U.S. Army Corp of Engineers
 - Approval of discharge of dredged or fill material into the waters of the United States under Section 404 of the Clean Water Act;
 - Approval of the construction of structures or work in navigable waters of the United States under Section 10 of the Rivers and Harbors Act of 1899;
2. Environmental Protection Agency
 - National Pollutant Discharge Elimination System (402) Permit;
 - Review Spill Prevention Control and Countermeasures Plan;
3. State of Alaska, Department of Natural Resources
 - Tideland Permit and Lease or Easement;
4. State of Alaska, Department of Environmental Conservation
 - Solid Waste Disposal Permit;
 - Certification of Compliance with Alaska Water Quality Standards (401 Certification)

Responsible Official: Bradley E. Powell, Forest Supervisor, Ketchikan Area, Tongass National Forest, Federal Building, Ketchikan, Alaska 99901, is the responsible official. The responsible official will consider the comments, response, disclosure of environmental consequences, and applicable laws, regulations, and policies in making the decision and stating the rationale in the Record of Decision.

Dated: July 25, 1997.

Bradley E. Powell,
Forest Supervisor.

[FR Doc. 97-21657 Filed 8-14-97; 8:45 am]

BILLING CODE 3410-11-M

DEPARTMENT OF AGRICULTURE

Forest Service

Eastern Washington Cascades Provincial Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of field tour.

SUMMARY: The Eastern Washington Cascades Provincial Advisory Committee will meet on September 24, 1997, at the Wenatchee National Forest Supervisors Office, 215 Melody Lane, Wenatchee, Washington. The Provincial Advisory Committee members will meet at the Supervisors Office at 9:00 a.m., then proceed to the field tour in the Leavenworth Ranger District (Beehive and Mission Creek areas). The tour will end at 4:00 p.m. This field tour will focus on dry forest management projects. All Eastern Washington

Cascades Province Advisory Committee meetings are open to the public. Interested citizens are welcome to attend.

FOR FURTHER INFORMATION CONTACT:

Direct questions regarding this meeting to Paul Hart, Designated Federal Official, USDA, Wenatchee National Forest, 215 Melody Lane, Wenatchee, Washington 98801, 509-662-4335.

Dated: August 5, 1997.

Sonny J. O'Neal,

Forest Supervisor, Wenatchee National Forest.

[FR Doc. 97-21626 Filed 8-14-97; 8:45 am]

BILLING CODE 3410-11-M

DEPARTMENT OF AGRICULTURE

Forest Service

Southwest Oregon Provincial Interagency Executive Committee (PIEC), Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of Meeting.

SUMMARY: The Southwest Oregon PIEC Advisory Committee will meet on August 26 at the Illinois Valley Visitor Center in Cave Junction, Oregon. The meeting will begin at 9:00 a.m. and continue until 5:00 p.m. The meeting will be primarily a field tour.

Agenda items to be covered include: (1) Marbled Murrelet habitat; (2) information management; (3) Regional Ecosystem Office presentation; (4) Forest Service and National Park local issues; (5) Oregon Caves tour; and (6) field stops for mining issues. All Province Advisory Committee meetings are open to the public. Interested citizens need to contact Chuck Anderson ahead of time for this field trip.

FOR FURTHER INFORMATION CONTACT:

Direct questions regarding this meeting to Chuck Anderson, Province Advisory Committee staff, USDA, Forest Service, Rogue River National Forest, 333 W. 8th Street, Medford, Oregon 97501, phone 541-858-2322.

Dated: August 7, 1997.

Charles J. Anderson,

Acting Forest Supervisor, Designated Federal Official.

[FR Doc. 97-21663 Filed 8-14-97; 8:45 am]

BILLING CODE 3410-11-M

DEPARTMENT OF AGRICULTURE

Forest Service

Yakima Provincial Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of field tour.

SUMMARY: The Yakima Provincial Advisory Committee will meet on September 25, 1997, at the Cle Elum Ranger District Office, 803 W. 2nd Street, Cle Elum, Washington. The Provincial Advisory Committee members will meet at the Ranger District Office at 9:00 a.m., then proceed to the field tour in the Swauk Creek drainage area. The tour will end at 4:00 p.m. This field tour will focus primarily on dry forest management projects. All Yakima Province Advisory Committee meetings are open to the public. Interested citizens are welcome to attend.

FOR FURTHER INFORMATION CONTACT:

Direct questions regarding this meeting to Paul Hart, Designated Federal Official, USDA, Wenatchee National Forest, 215 Melody Lane, Wenatchee, Washington 98801, 509-662-4335.

Dated: August 5, 1997.

Sonny J. O'Neal,

Forest Supervisor, Wenatchee National Forest.

[FR Doc. 97-21627 Filed 8-14-97; 8:45 am]

BILLING CODE 3410-11-M

DEPARTMENT OF AGRICULTURE

Grain Inspection, Packers and Stockyards Administration

United States Standards for Whole Dry Peas, Split Peas, and Lentils

AGENCY: Grain Inspection, Packers and Stockyards Administration, USDA.

ACTION: Notice with Opportunity to Comment.

SUMMARY: The Grain Inspection, Packers and Stockyards Administration (GIPSA) is proposing to revise the United States Standards for Whole Dry Peas, Split Peas and Lentils. Specifically, GIPSA is proposing to eliminate the classes Persian and Mixed lentils, and to establish a new class, Miscellaneous peas, and a new grading factor for lentils, Inconspicuous Admixture. GIPSA is proposing to change these standards to facilitate the marketing of peas and lentils.

DATES: Comments must be submitted on or before September 15, 1997.

ADDRESSES: Written comments may be submitted to Sharon Vassiliades at

GIPSA, USDA, STOP 3649, 1400 Independence Avenue, SW, Washington, DC 20250-3649; faxed to (202) 720-4628; or e-mailed to svassili@fgisd.usda.gov.

All comments received will be made available for public inspection at the above address during regular business hours (7 CFR 1.27(b)).

The current United States Standards for Whole Dry Peas, Split Peas and Lentils, along with the proposed changes, is available either through the above addresses or by accessing GIPSA's Home Page on the Internet at: www.usda.gov/gipsa/strulreg/standard.

FOR FURTHER INFORMATION CONTACT: Contact Sharon Vassiliades at (202) 720-1738.

SUPPLEMENTARY INFORMATION: Section 203(c) of the Agricultural Marketing Act of 1946, as amended, directs and authorizes the Secretary of Agriculture "to develop and improve standards of quality, condition, quantity, grade, and packaging and recommend and demonstrate such standards in order to encourage uniformity and consistency in commercial practices * * *." GIPSA is committed to carrying out this authority in a manner that facilitates the marketing of agricultural commodities and makes copies of official standards available upon request. The United States Standards for Whole Dry Peas, Split Peas and Lentils do not appear in the Code of Federal Regulations but are maintained by the U.S. Department of Agriculture.

GIPSA is proposing to change the United States Standards for Whole Dry Peas, Split Peas and Lentils using the procedures it published in the **Federal Register** on February 13, 1997 (62 FR 6705). Specifically, GIPSA is proposing to eliminate the classes Persian and Mixed lentils, and to establish a new class, Miscellaneous peas, and a new grading factor for lentils, Inconspicuous Admixture.

GIPSA representatives are continually meeting with pea and lentil producers, processors, handlers, and merchandisers concerning the U.S. Standards for Whole Dry Peas, Split Peas, and Lentils in order to gain a better understanding of their views on changes needed to improve the existing standards. On the basis of comments received and other available information, GIPSA is proposing several changes to the standards.

Classes of Lentils

The present U.S. Standards for Lentils provide for three classes of lentils: Lentils, Persian Lentils, and Mixed

Lentils. The class Lentils is defined as "All lentils of the Chilean type, with not more than 2.0 percent of Persian lentils." Persian lentils are defined as "All lentils of the Persian type, with not more than 2.0 percent of Chilean lentils." Mixed lentils are "Any mixture of lentils consisting predominately of Chilean lentils or of Persian lentils, which contains more than 2.0 percent of lentils other than those of the predominating class."

All lentils grown and marketed in the United States, regardless of their size, shape, or color, are considered to be of the Chilean type and classed as "Lentils." Furthermore, the class names "Persian lentils" and "Mixed lentils" are neither domestically nor internationally recognized terms. With the recent introduction of small-seeded Chilean types, there is an increased risk that such lentils may be misclassified as Persian lentils. This could confuse lentil importers and needlessly disrupt the market. To provide greater uniformity within the U.S. lentil standards, GIPSA is proposing to eliminate the classes Persian and Mixed lentils.

Inconspicuous Admixture

Lentils—like most other crops—are susceptible to field contamination by volunteer crops and weeds. Most such weeds can be controlled with herbicide solutions. However, even if reasonable measures are taken, some weed seeds, volunteer grain, and other undesirable plant material are usually harvested with the lentils. Small and large seeded weeds/grain can be easily removed from the thresher-run lentils (i.e., dockage) and seeds that are the same size as lentils can also be removed with relative ease (i.e., foreign material). But, seeds that are the same size, shape, and color as lentils are very difficult to virtually impossible to remove. Fortunately, packers, exporters, and end-users do not view seeds that closely mimic the appearance of lentils, such as *Vicia sativa* (commonly known as vetch, mimics, or rogue lentils), as being as detrimental to quality as dockage or foreign material. Hence, the U.S. lentil industry feels that such seeds should not be considered as foreign material, but as a separate factor.

The U.S. lentil industry is committed to quality and has encouraged producers to take all appropriate action to control the spread of lentil-mimics. To facilitate this process and to ensure that lentil quality is determined accurately, GIPSA is proposing to establish a new factor, Inconspicuous Admixture. This factor will be defined as "Any seed which is difficult to distinguish from a lentil,

including, but not limited to *Vicia sativa*."

U.S. Standards for Whole Dry Peas

The present U.S. Standards for Peas provide for five classes of peas: Smooth Green Dry peas, Smooth Yellow Dry peas, Wrinkled Dry peas, Winter Dry peas, and Mixed Dry peas. In recent years, several new types of peas have been developed or introduced that do not readily fit within any of the current classes. To better facilitate the marketing of these peas, GIPSA is proposing to revise the U.S. Standards for Whole Dry Peas to establish a new class, Miscellaneous peas. Accordingly, peas that are not otherwise classified in the standards would be classified and designated according to the commonly accepted commercial name for the pea, e.g., Marrowfat peas. These proposed standard changes were recommended to us and reviewed by the affected trade. Therefore, GIPSA is publishing these proposed standard changes with a 30-day comment period which will provide a sufficient amount of time for interested persons to comment on changes to the standards.

Authority: 7 U.S.C. 1621 et seq.

Dated: August 8, 1997.

James R. Baker,
Administrator.

[FR Doc. 97-21570 Filed 8-14-97; 8:45 am]

BILLING CODE 3410-EN-P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Plains Electric Generation and Transmission Cooperative, Inc.; Intent To Hold Public Workshops and Prepare an Environmental Assessment

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of intent to conduct public scoping workshops and prepare an Environmental Assessment.

SUMMARY: The Rural Utilities Service (RUS) intends to hold public scoping workshops and prepare an Environmental Assessment (EA) in connection with possible RUS financing assistance relating to a project proposed by Plains Electric Generation and Transmission Cooperative, Inc. (Plains), of Albuquerque, New Mexico. The project consists of the construction, operation and maintenance of a 230 kV transmission line from a proposed substation near Gladstone in Colfax County, New Mexico, to the Walsenburg Substation in Huerfano County, Colorado.

DATES: RUS will conduct five public scoping workshops as follows:

September 17, 1997

4:00-8:00 p.m.—Walsenburg City Hall, 525 S. Albert Street, Walsenburg, Colorado 81089.

September 18, 1997

4:00-8:00 p.m.—Trinidad Community Center, 1309 Beashoar Drive, Trinidad, Colorado 81082.

September 22, 1997

4:00-8:00 p.m.—Holiday Inn, 473 Clayton Road, Raton, New Mexico 87740.

September 23, 1997

4:00-8:00 p.m.—Springer Electric Cooperative, 420 Maxwell Avenue, Springer, New Mexico 87747.

September 24, 1997

4:00-8:00 p.m.—Clayton Air Park Convention Center, Cedar Road, Clayton, New Mexico 88415.

FOR FURTHER INFORMATION CONTACT:

Dennis E. Rankin, Engineering and Environmental Staff, Rural Utilities Service, 1400 Independence Avenue, S.W., Stop 1571, Washington, DC 20250, telephone (202) 720-1784, or Rick Precek, Plains Electric Generation and Transmission Cooperative, Inc., P.O. Box 6551, Albuquerque, New Mexico 87197, telephone (505) 889-7207.

SUPPLEMENTARY INFORMATION: Plains is proposing to construct approximately 115 miles of 230 kV transmission line from a new substation near Gladstone in Colfax County, New Mexico, to the Walsenburg Substation in Huerfano County, Colorado.

Alternatives to be considered by RUS include no action, local generation, system alternatives, transmission alternatives and alternative routes.

Comments regarding the proposed project may be submitted orally or in writing at the public scoping workshops or in writing no later than October 24, 1997, to RUS or Plains at the addresses provided in this notice.

Plains and its consultant have prepared an Alternative Evaluation and Macro-Corridor Study for the project. The Alternative Evaluation and Macro-Corridor Study is available for public review at RUS or Plains at the addresses provided in this notice. The documents can also be reviewed at Springer Electric Cooperative, Inc., Springer, New Mexico 87747; Southwestern Electric Cooperative, Inc., Clayton, New Mexico 88145; and in the libraries in the towns of Walsenburg and Trinidad, Colorado, and Raton, Clayton and Springer, New Mexico.

An Environmental Assessment will be prepared for the proposed project. Based on a review of the Environmental Assessment and other relevant information, RUS will determine if the preparation of an Environmental Impact Statement (EIS) is warranted. Should RUS determine that the preparation of an EIS is not warranted, it will prepare a Finding of No Significant Impact.

Any final action by RUS related to the proposed project will be subject to, and contingent upon, compliance with all relevant Federal environmental laws and regulations and completion of environmental review procedures as prescribed by the Council on Environmental Quality Regulations and RUS Environmental Policies and Procedures.

Dated: August 12, 1997.

Wally Beyer,

Administrator.

[FR Doc. 97-21655 Filed 8-14-97; 8:45 am]

BILLING CODE 3410-15-P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Distance Learning and Telemedicine Loan and Grant Program

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice; deadline for submission of grant and loan applications for FY 1997 funding.

SUMMARY: The Rural Utilities Service (RUS) is announcing that, in light of the current situation regarding the overburdened national delivery system, RUS will accept Distance Learning and Telemedicine loan and grant applications received after the August 12, 1997, deadline if the application is postmarked (or bears the equivalent) on or before August 11, 1997.

EFFECTIVE DATE: This notice is effective August 15, 1997.

SUPPLEMENTARY INFORMATION: On June 13, 1997, RUS amended 7 CFR Part 1703 by publishing revised subpart D, Distance Learning and Telemedicine Loan and Grant Program, in the **Federal Register**. In accordance with § 1703.113, applications requesting grant funding must be submitted to RUS to arrive no later than August 12, 1997, to be considered for fiscal year 1997 grant funding. Because of delays experienced in shipping parcels, RUS is concerned with the ability of applicants to secure the resources necessary to ensure that applications are received by RUS by the close of business, August 12, 1997. Therefore, RUS will accept Distance

Learning and Telemedicine loan and grant applications received after the August 12, 1997, deadline if the application is postmarked (or bears the equivalent) on or before August 11, 1997.

Authority: 7 U.S.C. 901 *et seq.* and 950aaa *et seq.*, Pub. L. 103-354, 108 Stat 3178 (7 U.S.C. 6941 *et seq.*).

Dated: August 8, 1997.

Wally Beyer,

Administrator, Rural Utilities Service.

[FR Doc. 97-21668 Filed 8-14-97; 8:45 am]

BILLING CODE 3410-15-M

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to the Procurement List.

SUMMARY: This action adds to the Procurement List commodities and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

EFFECTIVE DATE: September 15, 1997.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202-3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603-7740.

SUPPLEMENTARY INFORMATION: On March 7 and June 27, 1997, the Committee for Purchase From People Who Are Blind or Severely Disabled published notices (62 F.R. 10519 and 34686) of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the commodities and services and impact of the additions on the current or most recent contractors, the Committee has determined that the commodities and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46-48c and 41 CFR 51-2.4.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small

entities other than the small organizations that will furnish the commodities and services to the Government.

2. The action will not have a severe economic impact on current contractors for the commodities and services.

3. The action will result in authorizing small entities to furnish the commodities and services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46-48c) in connection with the commodities and services proposed for addition to the Procurement List.

Accordingly, the following commodities and services are hereby added to the Procurement List:

Commodities

Office and Miscellaneous Supplies

(Requirements for the Naval Training Center, Great Lakes, Illinois)

Services

Administrative Services

General Services Administration (FSS), 300 Ala Moana, Honolulu, Hawaii

Janitorial/Custodial

Davis-Monthan Air Force Base, Arizona

Janitorial/Custodial

Lake Mead National Recreation Area, Boulder City, Nevada

Laundry Service

Department of the Navy, Amphibious Group Three, San Diego, California

Mail and Messenger Service

U.S. Army Garrison-Fitzsimons, Aurora, Colorado

Operation of GSA Access Store

Philip Burton Federal Building and U.S. Courthouse, 450 Golden Gate Avenue, San Francisco, California

Operation of Postal Service Center

Seymour-Johnson Air Force Base, North Carolina

Switchboard Operation

Department of Veterans Affairs Medical Center, 400 Veterans Boulevard, Biloxi, Mississippi

This action does not affect current contracts awarded prior to the effective date of this addition or options that may be exercised under those contracts.

G. John Heyer,

General Counsel.

[FR Doc. 97-21643 Filed 8-14-97; 8:45 am]

BILLING CODE 6353-01-P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletion

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Additions to and Deletion from Procurement List.

SUMMARY: The Committee has received proposals to add to the Procurement List commodities and a service to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and to delete a service previously furnished by such agencies.

Comments must be received on or before: September 15, 1997.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202-3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603-7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51-2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

Additions

If the Committee approves the proposed addition, all entities of the Federal Government (except as otherwise indicated) will be required to procure the commodities and service listed below from nonprofit agencies employing persons who are blind or have other severe disabilities. I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities and service to the Government.

2. The action does not appear to have a severe economic impact on current contractors for the commodities and service.

3. The action will result in authorizing small entities to furnish the commodities and service to the Government.

4. There are no known regulatory alternatives which would accomplish

the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46-48c) in connection with the commodities and service proposed for addition to the Procurement List. Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

The following commodities and service have been proposed for addition to Procurement List for production by the nonprofit agencies listed:

Commodities

Towel, Paper, Industrial Wiping
7920-00-010-7106

NPA: East Texas Lighthouse for the Blind
Tyler, Texas

Towel, Machinery Wiping
7920-00-010-7156

NPA: East Texas Lighthouse for the Blind
Tyler, Texas

Cap, Camouflage, Desert

8415-01-326-1570 thru -1581

NPA: Southeastern Kentucky Rehabilitation
Industries, Inc.
Corbin, Kentucky

Service

Grounds Maintenance
Base Hospital
Buildings 5520, 5521 & 5522
Edwards Air Force Base, California
NPA: Desert Haven Enterprises, Inc.
Lancaster, California

Deletion

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action does not appear to have a severe economic impact on future contractors for the service.

3. The action will result in authorizing small entities to furnish the service to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46-48c) in connection with the service proposed for deletion from the Procurement List.

The following service has been proposed for deletion from the Procurement List:

Document Destruction
Internal Revenue Service
Cincinnati Service Center
Covington, KY

G. John Heyer,

General Counsel.

[FR Doc. 97-21645 Filed 8-14-97; 8:45 am]

BILLING CODE 6353-01-P

DEPARTMENT OF COMMERCE

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: Bureau of the Census.

Title: 1997 Company Organization Survey.

Form Number(s): NC-9901.

Agency Approval Number: 0607-0444.

Type of Request: Revision of a currently approved collection.

Burden: 90,832 hours.

Number of Respondents: 181,000.

Avg Hours Per Response: 30 minutes.

Needs and Uses: The Census Bureau conducts the annual Company Organization Survey (COS) in order to update and maintain a central, multipurpose business register, known as the Standard Statistical Establishment List (SSEL). In particular, the COS supplies critical information to the SSEL concerning the establishment composition, organizational structure, and operating characteristics of multi-establishment enterprises. The SSEL serves two fundamental purposes:

—First and most important, it provides sampling populations and enumeration lists for the Census Bureau's economic surveys and censuses, and it serves as an integral part of the statistical foundation underlying those programs. Essential for this purpose is the SSEL's ability to identify all known United States business establishments and their parent enterprises. Further, the SSEL must accurately record basic business attributes needed to control sampling and enumeration. These attributes include industrial and geographic classifications, measures of size and economic activity, ownership characteristics, and contact information (for example, name and address).

—Second, it provides establishment data that serve as the basis for the annual County Business Patterns (CBP) statistical series. CBP reports present data on number of establishments, first quarter payroll, annual payroll, and mid-March employment summarized by industry and employment size class for the United States, states, the District of Columbia, Puerto Rico, counties, and county-equivalents. No other annual or more frequent series of industry statistics provides comparable detail,

particularly for small geographic areas.

Affected Public: Business or other for-profit organizations.

Frequency: Annually.

Respondent's Obligation: Mandatory.

Legal Authority: Title 13 USC, Sections 131, 182, 224, and 225.

OMB Desk Officer: Jerry Coffey, (202) 395-7314.

Copies of the above information collection proposal can be obtained by calling or writing Linda Engelmeier, DOC Forms Clearance Officer, (202) 482-3272, Department of Commerce, room 5327, 14th and Constitution Avenue, NW, Washington, DC 20230.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to Jerry Coffey, OMB Desk Officer, room 10201, New Executive Office Building, Washington, DC 20503.

Dated: August 5, 1997.

Linda Engelmeier,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 97-21727 Filed 8-14-97; 8:45 am]

BILLING CODE 3510-07-P

DEPARTMENT OF COMMERCE

Bureau of the Census

Long Term Care Survey (LTC)

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Pub. L. 104-13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before October 14, 1997.

ADDRESSES: Direct all written comments to Linda Engelmeier, Departmental Forms Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Sarah Higgins, Bureau of the Census, FOB 3, Room 3356, Washington, DC 20233-8400, (301) 457-3801.

SUPPLEMENTARY INFORMATION:

I. Abstract

The LTC's general purpose is to characterize the health and functional status of the elderly population in the United States. The Census Bureau conducted LTC surveys in 1982, 1984, 1989, and 1994 under sponsorship from Duke University using funds received in a grant from the National Institute on Aging (NIA). Duke University and NIA propose the Census Bureau conduct a pretest in 1998 and the full scale survey again in 1999.

Duke University will use the data and combine it with the data collected from prior surveys to determine how people's health care needs change over time. Planners and policy makers also use data from the survey to conduct research to improve Medicare services and to plan for a sound future for the Medicare program.

Sample Overview

The survey sample has two components: "longitudinal" and "aged in". The *longitudinal* portion consists of 13,145 sample persons who responded to one or more of the previous four surveys. The *aged in* component consists of a total of 6,100 sample persons: 5,500 who turned 65 since the 1994 survey and an additional 600 people who are 95 years and over. The total sample size is 19,245. Part of the sample is designated as the "healthy" segment. The "healthy" segment has approximately 1,550 sample people. Half these people are retained from the longitudinal component and half are randomly selected from the aged in component. These healthy people respond to only part of the community questionnaire; they do not receive the questions about disability or impairment. The LTC survey consists of a screener interview and, potentially, a community or institutional interview.

Pretest

The Census Bureau with Duke University has decided to convert the LTC survey from a paper-and-pencil questionnaire to a computer-assisted personal interview (CAPI). We will conduct a pretest during the first half of fiscal year 1998 to test the CAPI instrument and survey procedures for the screener and community components. We will select 500 sample persons in the Tucson, Arizona area for the screener questionnaire, of which approximately 100 will "screen-in" for the detailed community questionnaire. In the latter part of fiscal year 1998, we will also conduct a small hothouse test for the institution CAPI instrument.

This test will include 40 respondents living in nursing homes in the surrounding Washington, DC area.

Survey Process

The Census Bureau's field representatives (FRs) conduct the screening interviews by telephone or by personal visit if the respondent cannot be reached by phone. FRs conduct all the community and institutional interviews through personal visits and capture data from the respondents via laptop computers. The Census Bureau transmits and stores the survey data on a microdata file and delivers the file to Duke University. Duke links the file with previous LTC data and appends it to administrative Medicare information. Duke sends copies of the file to the Michigan Archives on Aging. Duke analyzes the data and makes its findings known to NIA.

II. Method of Collection

The LTC will be conducted by both personal visits and telephone interviews using computer-assisted (laptop) interviewing. An advance letter will be sent to respondents notifying them of the upcoming survey.

III. Data

OMB Number: 0607-0778 (expired 9/30/95).

Form Number: There are no forms. We conduct all interviewing on laptop computers.

Type of Review: Regular.

Affected Public: Individuals.

Estimated Number of Respondents:

Fiscal Year 1998 (Pretest) 540.

Fiscal Year 1999 (Survey Year) 19,245.

Estimated Time Per Response:

Fiscal Year 1998 (Pretest) 23 minutes.

Fiscal Year 1999 (Survey Year) 31 minutes.

Estimated Total Annual Burden

Hours:

Fiscal Year 1998 (Pretest) 205.

Fiscal Year 1999 (Survey Year) 9,926.

Estimated Total Annual Cost: We do not expect respondents to incur any cost other than that of their time to respond.

Respondent's Obligation: Voluntary.

Legal Authority: Title 42, United States Code, Section 285e-1, and Title 15 United States Code, Section 1525 authorize this survey.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden

(including hours and cost) 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 submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: August 11, 1997.

Linda Engelmeier,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 97-21658 Filed 8-14-97; 8:45 am]

BILLING CODE 3510-07-P

DEPARTMENT OF COMMERCE

Bureau of Export Administration

Sensors and Instrumentation Technical Advisory Committee; Notice of Partially Closed Meeting

A meeting of the Sensors and Instrumentation Technical Advisory Committee will be held September 9, 1997, 9:00 a.m., in the Herbert C. Hoover Building, Room 1617M-2, 14th Street between Constitution and Pennsylvania Avenues, N.W., Washington, D.C. The Committee advises the Office of the Assistant Secretary for Export Administration with respect to technical questions that affect the level of export controls applicable to sensors and instrumentation equipment and technology.

Agenda:

General Session:

1. Opening remarks by the Chairman.
2. Update on the status of pending regulations.
3. Presentation of papers or comments by the public.

Executive Session:

4. Discussion of matters properly classified under Executive Order 12958, dealing with the U.S. export control program and strategic criteria related thereto.

The General Session of the meeting will be open to the public and a limited number of seats will be available. To the extent that time permits, members of the public may present oral statements to the Committee. Written statements may be submitted at any time before or after the meeting. However, to facilitate distribution of public presentation

materials to the Committee members, the Committee suggests that presenters forward the public presentation materials two weeks prior to the meeting date to the following address: Ms. Lee Ann Carpenter, OAS/EA MS: 3886C, Bureau of Export Administration, U.S. Department of Commerce, Washington, D.C. 20230.

The Assistant Secretary for Administration, with the concurrence of the General Counsel, formally determined on December 13, 1995, pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, that the series of meetings of the Committee and of any Subcommittees thereof, dealing with the classified materials listed in 5 U.S.C., 552b(c)(1) shall be exempt from the provisions relating to public meetings found in section 10(a)(1) and (a)(3), of the Federal Advisory Committee Act. The remaining series of meetings or portions thereof will be open to the public.

A copy of the Notice of Determination to close meetings or portions of meetings of the Committee is available for public inspection and copying in the Central Reference and Records Inspection Facility, Room 6020, U.S. Department of Commerce, Washington, D.C. 20230. For further information or copies of the minutes, contact Lee Ann Carpenter on (202) 482-2583.

Dated: August 12, 1997.

Lee Ann Carpenter,

Technical Advisory Committee Unit.

[FR Doc. 97-21664 Filed 8-14-97; 8:45 am]

BILLING CODE 3510-DT-M

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 914]

Approval For Manufacturing Authority, Baker Refractories, Inc. (Refractory Products) Within Foreign-Trade Zone 147; York, PA

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a-81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, § 400.28(a)(2) of the Board's regulations, requires approval of the Board prior to commencement of new manufacturing/processing activity within existing zone facilities;

Whereas, the Foreign Trade Zone Corporation of Southeastern Pennsylvania, grantee of FTZ 147, has requested authority under § 400.28(a)(2) on behalf of Baker Refractories, Inc., to manufacture refractory bricks under

zone procedures within FTZ 147, York, PA (filed 10-18-96; FTZ Doc. 77-96, 61 FR 55955, 10-30-96);

Whereas, the examiner's report recommends approval, finding that the requirements of the Act and the Board's regulations have been met and that the proposal is in the public interest; and,

Whereas, the Board adopts the findings and recommendations of the examiner's report;

Now, therefore, the Board hereby approves the request subject to the Act and the Board's regulations, including § 400.28, for a five-year period (until 12-31-02), subject to extension upon review.

Signed at Washington, DC, this 6th day of August 1997.

Foreign-Trade Zones Board.

Robert S. LaRussa,

Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

Attest:

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 97-21715 Filed 8-14-97; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 63-97]

Foreign-Trade Zone 183—Austin, Texas; Application for Expansion

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Foreign Trade Zone of Central Texas, Inc., grantee of FTZ 183, requesting authority to expand its zone in the Austin, Texas, area, within the Austin Customs port of entry. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a-81u), and the regulations of the Board (15 CFR Part 400). It was formally filed on August 4, 1997.

FTZ 183 was approved on December 23, 1991 (Board Order 550, 57 FR 42; 1/2/92). The zone currently consists of seven sites in the Austin, Texas, area:

Site 1—Austin Enterprise site (317 acres), consisting of seven parcels within the Austin Enterprise Zone Area along Highway 290 and the Ben White Boulevard-Montopolis Drive area, Austin;

Site 2—Balcones Research site (50 acres), located in north central Austin at the intersection of Burnett Road and Longhorn Boulevard;

Site 3—High Tech Corridor site (394 acres), consisting of five parcels located along I-35, 14 miles north of downtown Austin (site straddles Austin-Round Rock city line);

Site 4—Cedar Park site (122 acres), some eight miles northwest of the Austin city limits, in Williamson County;

Site 5—Round Rock "SSC" site (246 acres), consisting of two parcels located along I-35 between Chandler Road and Westinghouse Road on the northern edge of the City of Round Rock;

Site 6—Georgetown site (246 acres), located along I-35 and U.S. 81, south of downtown Georgetown;

Site 7—San Marcos site (40 acres), located within the San Marcos Municipal Airport facility in eastern San Marcos, adjacent to State Highway 21, on the Hays County/Caldwell County line.

(An expansion request (Doc. 30-97) is currently pending with the FTZ Board to expand Site 3 to include 368 acres (5 contiguous tracts) located within the City of Round Rock, adjacent to Site 3's eastern boundary)

The applicant is now requesting authority to expand FTZ 183 to include the MET Center industrial park (200 acres) located between U.S. Highway 183 South and State Highway 71 East in southeast Austin, some 5 miles northwest of the new Austin Bergstrom International Airport. No specific manufacturing requests are being made at this time. Such requests would be made to the Board on a case-by case basis.

In accordance with the Board's regulations, a member of the FTZ Staff has been designated examiner to investigate the application and report to the Board.

Public comment on the application is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is October 14, 1997. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to October 29, 1997).

A copy of the application and accompanying exhibits will be available for public inspection at each of the following locations:

U.S. Department of Commerce, Export Assistance Center, 1700 Congress, 2nd Floor, Austin, Texas 78701

Office of the Executive Secretary, Foreign-Trade Zones Board, U.S. Department of Commerce, Room 3716, 14th and Pennsylvania Avenue, NW., Washington, DC 20230

Dated: August 8, 1997.

John J. DaPonte, Jr.,
Executive Secretary.

[FR Doc. 97-21714 Filed 8-14-97; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-427-098]

Anhydrous Sodium Metasilicate From France; Notice of Termination of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of termination of antidumping duty administrative review.

SUMMARY: On March 3, 1997, the Department of Commerce ("the Department") published in the **Federal Register** (62 FR 1874) a notice announcing the initiation of an administrative review of the antidumping duty order on anhydrous sodium metasilicate (ASM) from France. The initiation was in response to a request for review by the petitioner, the PQ Corporation. This review covers Rhone-Poulenc, a manufacturer/exporter of ASM, and the period of review (POR) from January 1, 1996 through December 31, 1996. However, we are terminating this review as a result of the absence of entries into the United States of subject merchandise manufactured/exported by Rhone-Poulenc.

EFFECTIVE DATE: August 15, 1997.

FOR FURTHER INFORMATION CONTACT: Mark Ross or Richard Rimlinger, 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.

SUPPLEMENTARY INFORMATION:

The Applicable Statute

Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended (the Tariff Act), are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act by the Uruguay Round Agreements Act.

Background

The Department published in the **Federal Register** on January 14, 1997 (62 FR 1874) a "Notice of Opportunity to Request Administrative Review" of the antidumping duty order on ASM from France (46 FR 1667, January 7, 1981). On January 28, 1997, the petitioner requested an administrative review of Rhone-Poulenc, a manufacturer/exporter of ASM. The Department initiated the review on

March 3, 1997 (62 FR 9413). On April 2, 1997, Rhone-Poulenc filed a letter explaining that it did not export any subject merchandise to the United States during the POR. On April 10, 1997, the Department sent a no-shipment inquiry regarding Rhone-Poulenc to the U.S. Customs Service. The purpose of this inquiry was to determine whether the U.S. Customs Service suspended liquidation of entry summaries of this merchandise during the period. Because the U.S. Customs Service did not identify any suspended entry summaries of ASM manufactured/exported by Rhone-Poulenc during the POR, we have determined that no entries into the customs territory of the United States occurred during the POR. Therefore, we are terminating this review. The cash deposit rate for Rhone-Poulenc will remain at 60 percent, the rate established in the most recently completed segment of this proceeding (61 FR 44038, August 27, 1996).

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 (1997).

Dated: August 7, 1997.

Richard W. Moreland,

Acting Assistant Secretary for Import Administration.

[FR Doc. 97-21713 Filed 8-14-97; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-433-807]

Notice of Final Determination of Sales at Less Than Fair Value: Open-End Spun Rayon Singles Yarn From Austria

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: August 15, 1997.

FOR FURTHER INFORMATION CONTACT: Russell Morris or Robert Copyak, Office of CVD/AD Enforcement VI, Import Administration, International Trade Administration, U.S. Department of Commerce, Room 4012, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone (202) 482-2786.

The Applicable Statute

Unless otherwise indicated, all citations to the statute are references to the provisions of the Tariff Act of 1930, as amended by the Uruguay Round Agreements Act effective January 1, 1995 (the "Act"). In addition, unless otherwise indicated, all citations to the

Department's regulations are to 19 CFR Part 353 (1997).

Final Determination

We determine that open-end spun rayon singles yarn from Austria is being, or is likely to be, sold in the United States at less than fair value ("LTFV"), as provided in section 735 of the Act.

Case History

Since the preliminary determination in this investigation (Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination: Open-End Spun Rayon Singles Yarn from Austria, (62 FR 14399 (March 26, 1997))), the following events have occurred:

In May, we verified the questionnaire responses of respondents, Linz Textil GmbH (Linz) and G. Borckenstein und Sohn A.G. (Borckenstein). Petitioner, The Ad-Hoc Committee of Open-End Rayon Yarn Producers, and respondents submitted case briefs on June 30, 1997, and rebuttal briefs on July 7, 1997.

Scope of Investigation

The investigation covers all items of open-end spun singles yarn containing 85% or more rayon staple fiber. The merchandise is classifiable under subheading 5510.11.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading is provided for convenience and for Customs purposes, our written description of the scope of this investigation is dispositive.

Period of Investigation

The period of investigation (POI) is July 1, 1995 through June 30, 1996.

Fair Value Comparisons

To determine whether sales to the United States of the subject merchandise by respondents were made at less than fair value, we compared the Export Price ("EP") to the Normal Value ("NV"), as described in the "Export Price" and "Normal Value" sections of this notice. As set forth in section 773(a)(1)(B)(i) of the Act, we calculated NV based on sales at the same level of trade as the U.S. sale. In accordance with section 777A(d)(1)(A)(i), we compared the weighted average EPs to weighted-average NVs during the POI. In determining averaging groups for comparison purposes, we considered the appropriateness of such factors as physical characteristics.

1. Physical Characteristics

In accordance with section 771(16) of the Act, we considered all products covered by the description in the

"Scope of Investigation" section, above, produced in Austria by the respondents and sold in the home market during the POI, to be foreign like product for purposes of determining appropriate product comparisons to U.S. sales. Where there were no sales of identical merchandise in the home market to compare to U.S. sales, we compared U.S. sales to the most similar foreign like product on the basis of the characteristics listed in the Department's antidumping questionnaire. In making the product comparisons, we relied on the following criteria (listed in order of preference): weight, percentage of rayon fiber, color, denier, finish, and luster. All comparisons were based on the same grade of yarn.

2. Level of Trade

In the preliminary determination, the Department determined that no difference in level of trade existed between home market and U.S. sales for either Borckenstein or Linz (Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination: Open-End Spun Rayon Singles Yarn from Austria, (62 FR 14399 (March 26, 1997))). Our findings at verification confirmed that Borckenstein and Linz performed essentially the same selling activities for all reported home market and U.S. sales. Accordingly, we determine that all price comparisons are at the same level of trade and an adjustment pursuant to section 773(a)(7)(A) is unwarranted.

Export Price

We calculated EP, in accordance with subsections 772 (a) and (c) of the Act, for each of the respondents, where the subject merchandise was sold directly to the first unaffiliated purchaser in the United States prior to importation and use of constructed export price (CEP) was not otherwise warranted based on the facts of record.

We made company-specific adjustments as follows:

1. Linz

We calculated EP based on packed, delivered/duty paid and f.o.b. prices to unaffiliated customers in the United States. Where appropriate, we made deductions from the starting price (gross unit price) for the following charges: Austrian inland freight (which included brokerage), insurance (which included inland and marine insurance), ocean freight, U.S. duty, clearing charges, bond expenses, U.S. freight and post-sale warehousing, in accordance with section 772(c)(2).

Linz reported that it did not borrow in U.S. dollars during the POI. In accordance with the Department's policy (*see, e.g.,* Notice of Final Results of Antidumping Duty Administrative Review: Certain Cut-to-Length Carbon Steel Plate from Sweden, (61 FR 15780, April 9, 1996)), we recalculated the U.S. imputed credit expense using the average short-term lending rates published by the Federal Reserve as surrogate U.S. interest rates, for purposes of making the circumstance of sale adjustment for this expense. In addition, in the preliminary determination, we treated post-sale warehousing as a circumstance of sale adjustment. For the final determination, we have deducted post-sale warehousing from the export price because it is a movement expense (*see, e.g.,* Certain Stainless Steel Wire Rods from France: Final Results of Antidumping Duty Administrative Review, (62 FR 7206, February 18, 1997)).

Based on our verification findings, we deducted an additional small movement expense, called the "vorlage," which Linz had omitted in reporting movement charges to the United States (*see* Comment 2).

2. Borckenstein

For Borckenstein, we calculated EP based on packed, CIF, U.S. port prices to an unaffiliated customer in the United States. Where appropriate, we made deductions from the starting price (gross unit price) for international freight (which included freight from the plant to port of export and ocean freight) and marine insurance, in accordance with section 772(c)(2)(A).

We have considered petitioner's request to use CEP. Based on our analysis and verification findings, however, we do not find that sufficient evidence exists to indicate that the sole U.S. importer and Borckenstein are affiliated parties. Pursuant to section 771(33) of the Act, we reviewed Borckenstein's relationship with the U.S. importer during verification and determined that petitioner's claim is unwarranted (*see* Comment 10).

We made the following correction, based on our verification findings. In our preliminary determination, we treated the U.S. commissions paid by Borckenstein to its U.S. selling agent as rebates. Upon a thorough review of documentation during verification, and our analysis of arguments from interested parties, we have determined that the fee paid by Borckenstein to its selling agent on U.S. sales is a commission (*see* Comment 14).

Normal Value

Cost of Production Analysis

As discussed in the preliminary determination, the Department found reasonable grounds to believe or suspect that Linz's and Borckenstein's sales in the home market were made at prices below the cost of producing the merchandise. As a result, the Department initiated an investigation to determine whether Linz and Borckenstein had made home market sales during the POI at prices below their respective cost of production ("COP") within the meaning of section 773(b) of the Act. Although the Department was unable to include a COP analysis of Borckenstein's home market sales in the preliminary determination, the final determination does include a COP analysis of Borckenstein's home market sales.

Before making any fair value comparisons, we conducted the COP analysis described below for each company:

1. Linz

A. Calculation of COP

We calculated the COP based on the sum of Linz's cost of materials and fabrication for the foreign like product, plus amounts for home market selling, general and administrative expenses ("SG&A") and packing costs in accordance with section 773(b)(3) of the Act.

In calculating Linz's SG&A, we adjusted the submitted net interest expense amount to include only short-term interest income as an offset (see Comment 8).

B. Test of Home Market Prices

We compared the respondent's submitted POI weighted-average COP figures, as adjusted, to home market sales of the foreign like product as required under section 773(b) of the Act, in order to determine whether these sales had been made at below-cost prices within an extended period of time in substantial quantities, and whether the below-cost prices would permit recovery of all costs within a reasonable period of time. On a product-specific basis, we compared the COP to the home market prices, less any applicable movement charges and direct selling expenses. As in our preliminary determination, we did not deduct indirect selling expenses from the home market price because these expenses were included in the SG&A rate for COP.

C. Results of COP Test

Pursuant to section 773(b)(2)(C) of the Act, where less than 20 percent of a respondent's sales of a given product are at prices less than COP, we do not disregard any below-cost sales of that product because we determined that the below-cost sales were not made in "substantial quantities." Where 20 percent or more of a respondent's sales of a given product during the POI are at prices less than the COP, we determine such sales to have been made in "substantial quantities" within an extended period of time in accordance with section 773(b)(2)(B) of the Act, and not made at prices which would permit recovery of all costs within a reasonable period of time, in accordance with section 773(b)(2)(D) of the Act. In such cases, we disregard the below-cost sales. Under the Department's practice, when all sales of a specific product are at prices below the COP, we disregard all sales of that product, and calculate NV based on constructed value ("CV").

Based on our COP test, we found that less than 20 percent (by quantity) of Linz's sales of a given product were at less than COP. Thus, we did not disregard any below-cost sales. For matching purposes, export prices were compared to home market prices for all comparisons, and CV was not required.

D. Price to Price Comparison

We calculated NV based on packed, delivered prices to unaffiliated customers and prices to affiliated customers where the sales were made at arm's length. Where appropriate, we made deductions from the starting price (gross unit price) for foreign inland freight and inland insurance, in accordance with section 773(a)(6)(B). In addition, where appropriate, we adjusted for differences in circumstances of sale for credit expenses and commissions (including appropriate offsets), in accordance with section 773(a)(6)(C)(iii). We also deducted home market packing costs and added U.S. packing costs, in accordance with section 773(a)(6) (A) and (B) of the Act. We made adjustments, where appropriate, for physical differences in the merchandise in accordance with section 773(a)(6)(C)(ii) of the Act. In no case did the difference in merchandise adjustment for the comparison product exceed 20 percent of the U.S. product's cost of manufacturing.

For purposes of the difference in merchandise adjustment, Linz reported a different cost of manufacturing for identical yarns due to the fact that different machines produce the yarn.

Since the difference in merchandise adjustment is intended to account for physical differences in similar merchandise being compared and not differences in the production process, we have calculated a single weighted-average cost of manufacturing for identical yarns.

Linz also reported an amount upon which to base an adjustment for differences in quantities sold in the United States and Austrian markets. However, Linz was unable to demonstrate, based on information on the record, that pricing differences were related to quantity. Accordingly, we have not made the requested adjustment (see Comment 6).

Linz was instructed to provide sales made to affiliated weaving mills in Austria (see Comment 5). We tested these sales to ensure that the affiliated party sales were at arm's-length. To conduct this test, we compared the starting prices of sales to affiliated and unaffiliated customers net of all movement charges, direct selling expenses, and packing. We utilized the 99.5 percent benchmark ratio used in the 1993 carbon steel investigations. See, e.g., Final Determination of Sales at Less Than Fair Value: Certain Cold-Rolled Carbon Steel Flat Products from Argentina (58 FR 37062, 37077 (July 9, 1993)). Where no affiliated customer price ratio could be constructed because identical merchandise was not sold to unaffiliated customers, we were unable to determine that these sales were made at arm's-length and, therefore, we excluded them from our LTFV analysis.

We made the following corrections, based on our verification findings. For the preliminary determination, Linz did not report home market indirect selling expenses; therefore, we were unable to offset commissions paid in the United States with home market indirect selling expenses. Subsequent to the preliminary determination, Linz submitted its indirect selling expenses. However, we were unable to verify the full amount of Linz's claimed home market indirect selling expenses, and have recalculated the allowable portion of indirect selling expenses to be used as an offset to the U.S. commission (see Comment 3).

During verification, we discovered the interest rate used to calculate home market credit expenses was based on long-term lending. However, we did find that the company maintained two lines of credit for export sales during the POI. Although these lines of credit are based on a percentage of the company's annual export turnover, the company can borrow against these lines of credit to finance more than just exports. The credit lines are available for financing

current assets and liabilities and the interest rates charged are set on a quarterly basis. Therefore, we have recalculated Linz's home market credit expenses based upon the average interest rate charged on these lines of credit in order to reflect the company's actual short-term borrowing experience.

2. Borckenstein

A. Calculation of COP

We calculated the COP based on the sum of Borckenstein's cost of materials and fabrication for the foreign like product, plus amounts for home market selling, general and administrative expenses (SG&A) and packing costs in accordance with section 773(b)(3) of the Act.

We adjusted Borckenstein's depreciation expense to include depreciation expense for all categories of fixed assets used in the production of the subject merchandise and for assets used to perform the administrative functions of the company (see Comment 15).

B. Test of Home Market Prices

We compared the respondent's submitted POI weighted-average COP figures, as adjusted, to home market sales of the foreign like product as required under section 773(b) of the Act in order to determine whether these sales had been made at below-cost prices within an extended period of time in substantial quantities, and were not at prices which permit recovery of all costs within a reasonable period of time. On a model-specific basis, we compared the COP to the home market prices, less any applicable movement charges and direct selling expenses. We deducted indirect selling expenses from the home market price because these expenses were not included in the G&A rate for COP.

C. Results of COP Test

Pursuant to section 773(b)(2)(C) of the Act, where less than 20 percent of a respondent's sales of a given product are at prices less than COP, we do not disregard any below-cost sales of that product because we determined that the below-cost sales were not made in "substantial quantities." Where 20 percent or more of a respondent's sales of a given product during the POI are at prices less than the COP, we determine such sales to have been made in "substantial quantities" within an extended period of time in accordance with section 773(b)(2)(B) of the Act, and that such sales are not made at prices which would permit recovery of all costs within a reasonable period of time, in accordance with section 773(b)(2)(D)

of the Act. In such cases, we disregard the below-cost sales. Under the Department's practice, when all sales of a specific product are at prices below the COP, we disregard all sales of that product, and calculate NV based on CV.

Based on our COP test, we found that less than 20 percent (by quantity) of Borckenstein's sales of a given product were at less than COP. Thus, we did not disregard any below-cost sales. For matching purposes, export prices were compared to home market prices for all comparisons, and CV was not required.

D. Price to Price Comparisons

We calculated NV based on packed, delivered prices to unaffiliated customers. Where appropriate, we made deductions from the starting price (gross unit price) for foreign inland freight and inland insurance, in accordance with section 773(a)(6)(B). In addition, where appropriate, we adjusted for differences in circumstances of sale for credit expenses, export credit insurance, and commissions (including appropriate offsets), in accordance with section 773(a)(6)(C)(iii). We also deducted home market packing costs and added U.S. packing costs, in accordance with section 773(a)(6)(A) and (B) of the Act. We made adjustments, where appropriate, for physical differences in the merchandise in accordance with section 773(a)(6)(C)(ii) of the Act. In no case did the difference in merchandise adjustment for the comparison product exceed 20 percent of the U.S. product's cost of manufacturing.

Borckenstein also reported an amount upon which to base an adjustment for differences in quantities sold in the U.S. and Austrian markets, pursuant to 19 CFR 353.55(b). Although Borckenstein claimed that it incurred differing manufacturing costs based on quantities produced, it was unable to demonstrate, based on information on the record, that pricing differences were related to quantity. Our review of the submitted prices indicated that prices did not vary based upon the quantity sold.

Accordingly, we have not made the requested adjustment (see Comment 11).

We made the following modification to the calculations for the final determination. In our preliminary determination, we treated the U.S. commissions paid by Borckenstein to its U.S. selling agent as rebates. As a result, there was no offset for indirect selling expenses in the home market. Upon a thorough review of documentation during verification, we have determined that the fee paid by Borckenstein to its selling agent on U.S. sales is a commission. Therefore, we have offset the U.S. commission with

Borckenstein's home market indirect selling expenses (see Comment 14).

Currency Conversion

We made currency conversions into U.S. dollars based on the official exchange rates in effect on the dates of the U.S. sales as certified by the Federal Reserve Bank.

Section 773A(a) of the Act directs the Department to convert foreign currencies based on the dollar exchange rate in effect on the date of sale of the subject merchandise, except if it is established that a currency transaction on forward markets is directly linked to an export sale. When a company demonstrates that a sale on forward markets is directly linked to a particular export sale in order to minimize its exposure to exchange rate losses, the Department will use the rate of exchange in the forward currency sale agreement.

Section 773A(a) also directs the Department to use a daily exchange rate in order to convert foreign currencies into U.S. dollars unless the daily rate involves a fluctuation. It is the Department's practice to find that a fluctuation exists when the daily exchange rate differs from the benchmark rate by 2.25 percent. The benchmark is defined as the moving average of rates for the past 40 business days. When we determine a fluctuation to have existed, we substitute the benchmark rate for the daily rate, in accordance with established practice. Further, section 773A(b) directs the Department to allow a 60-day adjustment period when a currency has undergone a sustained movement. A sustained movement has occurred when the weekly average of actual daily rates exceeds the weekly average of benchmark rates by more than five percent for eight consecutive weeks, see Change in Policy Regarding Currency Conversions 61 FR 9434 (March 8, 1996). Such an adjustment period is required only when a foreign currency is appreciating against the U.S. dollar. The use of an adjustment period was not warranted in this case because the Austrian Schilling did not undergo a sustained movement.

Verification

As provided in section 782(i) of the Act, we verified the information submitted by the respondents for use in our final determination. We used standard verification procedures, including examination of relevant accounting and production records and original source documents provided by respondents.

Interested Party Comments*Linz**Comment 1: Comparison of Sales of Second-Quality Merchandise*

Petitioner asserts that the comparison of sales of second-quality merchandise in the home market to first quality export sales to the U.S. is inconsistent with the Department's standard practice. Accordingly, petitioner claims that the Department should revise its preliminary results to ensure that first quality and second quality merchandise are treated as distinct products in the Department's margin program for purposes of the final determination. Linz argues that the Department should include Linz's sales to the home market of second-quality merchandise in the margin calculation.

DOC Position: The petitioner is correct that it is the Department's policy to compare U.S. and home market merchandise of comparable quality. *See, e.g.,* Notice of Final Results of Antidumping Administrative Review: Porcelain on Steel Cookware from Mexico, 62 FR 25908 (May 12, 1997). Only first quality merchandise was sold in the U.S. market. Therefore, for purposes of this final determination, first quality products sold in the United States were compared only to first quality merchandise sold in the home market.

Comment 2: Movement Expenses

The petitioner contends that Linz failed to fully report all of its movement expenses to the United States. Petitioner states that the Department discovered that Linz failed to report the "vorlage" freight expenses incurred in transporting merchandise to the United States during verification. As a result, the Department should account for this unreported expense by applying, as facts available, an adjustment for this expense to be deducted from the price of each U.S. sale. Linz asserts that the Department should not adjust all U.S. sales for a movement expense that may not have actually been incurred. Linz states that this expense is not found on the invoices of all freight forwarders.

DOC Position: During verification, the Department discovered that Linz had inadvertently failed to report a minor freight expense incurred in transporting merchandise to the United States. This expense, called "vorlage," was part of the company's freight bill. This expense was reported on all of the freight bills reviewed by the Department for U.S. sales. Therefore, during verification, we collected several U.S. freight bills and calculated the average "vorlage"

charged on U.S. sales. We have deducted the average "vorlage" expense from the sales price of all U.S. sales as "facts available" in accordance with section 776(a) of the Act.

Comment 3: Commission Offset

Petitioner argues that Linz's estimated indirect selling expenses were not verified, and, thus, cannot be used as a commission offset. Petitioner contends that there are two problems with Linz's estimated indirect selling expense, and, therefore, only the general indirect selling expense was properly calculated and should be included in the Department's margin calculation. First, petitioner states that all of Linz's estimated indirect selling expenses were fully captured in the general expense amount and that creation of an additional expense estimate is not warranted. Second, the Department was unable to verify the allocation method of the estimated selling expenses to domestic sales at verification.

Linz argues that it arrived at a general per unit indirect selling amount applicable to all sales and then adjusted this amount to reflect the proportion allocated to home market sales for which no separate selling agents are involved. Linz states that this allocation is reasonable and properly accepted based upon the stated experience of the sales manager.

DOC Position: We agree with the petitioner. Commissions are paid on U.S. sales but none are paid on home market sales. In our preliminary determination, the Department did not perform a commission offset, pursuant to 19 CFR section 353.56(b), as Linz had not provided information on its indirect selling expenses in the home market. After the preliminary determination, Linz provided an amount for home market indirect selling expenses. Linz reported two indirect selling expense amounts: a general indirect selling expense amount and an additional estimated home market indirect selling expense amount.

At verification, Linz explained how it calculated its estimated indirect selling expenses incurred on home market sales. Linz stated that beginning with a total indirect selling amount that captures the expenses for all production (open-end and ring-spun yarn), Linz arrived at a general per unit amount applicable to all sales on a global scale. It then adjusted this amount to reflect the proportion attributable solely to home market sales. Linz estimated that only 20 percent of indirect selling must be allocated to home market sales because there are no selling agents in their domestic market. We requested to

review worksheets to determine how they calculated this percentage. Linz stated that no worksheets were used in this calculation. Because no worksheets were used to calculate this portion of indirect selling expenses that Linz claimed to be attributed to home market sales, and because they were unable to tie the estimate to any source documentation, the Department cannot consider this additional estimated home market selling expense as verified. Therefore, we are not allowing this portion of the indirect selling expense adjustment. However, because we were able to verify the general indirect selling expense claim, we have used that amount as the basis of the commission offset.

Comment 4: Granting of Early Payment Discount

Petitioner contends that Linz's early payment discounts on home market sales should not be granted to customers that did not meet the terms of the discount program. Petitioner states that Linz applied an early payment discount to a number of sales where payment was not made within the requisite time period, as agreed upon in the terms of payment. Linz states that the Department should subtract all early payment discounts from the normal value, regardless of whether payment was made within the time period specified in the payment terms.

DOC Position: At verification, the Department carefully reviewed the customer accounts involving early payment discounts, both those taken within and outside the requisite time period, and found that the discounts were in fact granted. Because we verified that the discounts were given on the sales, we have taken them into account in this final determination.

Comment 5: Deficiencies With Affiliated Sales

Petitioner argues that there are significant errors in Linz's revised data file for sales to affiliates in the home market. Petitioner states that in submitting its revised data, Linz did not report gross price, sales date, pay date, rebates, discounts, rebates or credit expenses. Petitioner states that the Department was forced to verify Linz's revised affiliated sales during verification and that none of the reported sales to affiliates were traced for accuracy during verification. Thus, petitioner argues that the Department should employ the use of facts available in analyzing Linz's sales to affiliated parties in the home market. At a minimum, the Department should deny

the unverified adjustments claimed by Linz.

Linz states that nowhere in the Department's verification report does the Department state that it could not verify any adjustment. Linz states that the verification team reviewed the affiliated party sales extensively because of a "data sort" problem encountered and corrected at verification. Linz asserts that the verification team checked the records of these sales through numerous sales traces.

DOC Position: During verification, we discovered that there was a problem with the data base for Linz's home market affiliated sales. This problem was caused during a "data sort" for the affiliated data base used in our preliminary determination. The company only resorted the first few fields in the data base, while the other data fields remained in the original order. This caused the observation numbers to be out of sequential order and, thus, the information on pricing and expenses were unrelated to the specified sale in the data base. After discovering this error at verification, Linz correctly sorted the data fields and provided a corrected affiliated party sales listing.

We collected this revised affiliated party sales listing as a verification exhibit. The price reported in this sales listing was less the early payment discount. The sales listing also reported the freight expenses. The Department then verified this corrected data base and traced the information reported on these affiliated party sales to source documents. Thus, we verified the accuracy of the revised home market affiliated party sales data base and have used it where appropriate in this final determination. However, because the company did not report any other adjustment for these sales, the only deductions made from the starting price were for early payment discounts and freight expense.

Comment 6: Quantity Adjustment Under Section 353.55(b)

Linz has requested recognition of quantity price adjustments under § 353.55(b)(1) of the Department's regulations. Linz states that it has supplied the Department with information to show that its small quantity price adjustment policy was motivated by a commercial need to equalize the per-unit administrative expenses of processing large and small quantity orders. Linz further states that it has demonstrated that the amount of any price differential is wholly or partially due to the differences in quantities sold in the two markets, and

that it has demonstrated that the small quantity price adjustment was consistently applied on a majority of its home market sales in the POI.

Petitioner argues that there is no basis to grant Linz's claim of a small quantity surcharge. Petitioner states that Linz was unable to verify the accuracy or relevance of their internal memorandum on low volume sales, which serves as the basis for Linz's claim. They state that prices and quantities in the home market were inconsistent with the guidelines established by Linz for the low quantity price add-ons. Thus, there has been no demonstration that price increases for small quantity sales were applied in a consistent manner as required by Department policy.

DOC Position: Pursuant to 19 CFR 353.55(b), "The Secretary will calculate foreign market value based on sales with quantity discounts if:

(1) During the period examined or during a more representative period, the producer or reseller granted quantity discounts of at least the same magnitude on 20 percent or more of sales of such or similar merchandise for the relevant country [Six-Month Rule]; or

(2) the producer demonstrates to the Secretary's satisfaction that the discounts reflect savings specifically attributable to the production of different quantities [Cost Justification Method]."

The Department expounded upon its requirements for including quantity discounts in its analysis in Final Determination of Sales at Less Than Fair Value: Brass Sheet and Strip from the Netherlands, (Brass Sheet and Strip) 53 FR 23431 (June 22, 1988). The Department asserted that:

to be eligible for a quantity-based adjustment [six-month rule], a respondent must demonstrate a clear and direct *correlation between price differences and quantities sold or costs incurred*. This requirement applies equally to an allowance for quantity differences under the six-month rule or the cost justification requirement. Under the six-month rule, it is not sufficient that, during the POI, the respondent merely granted discounts of at least the same magnitude with respect to 20 percent or more of such or similar merchandise sold in the *ordinary course of trade* in the market used to establish foreign market value[;] the exporter must also demonstrate, using evidence such as a *price list or quantity discount schedule*, that it gave discounts on a *uniform basis* and that such discounts were *available to substantially all home market customers*. With regard to a cost-based adjustment, the exporter must demonstrate that the discounts are warranted on the basis of savings which are specifically attributable to the production of the different quantities involved. (Emphasis added)

Linz has specified that it is seeking to include a small quantity surcharge under the Department's so-called "six-

month" rule, contained in Section 353.55(b)(1) of the Department's regulations. The Department requires consistency under this rule in two respects: The first is whether or not price increases were applied when appropriate. The second is whether or not price increases, when applied, were applied consistently in accordance with the pricing policy.

Linz stated that, for small quantity purchasers in the home market, it adds a small quantity price add-on to account for the additional administrative expenses incurred in servicing small quantity purchasers. Linz based its claimed small quantity surcharge on a September 1992 internal memorandum on low volume sales. This memorandum specifies four small quantity categories with a specified price increase for each of the quantity brackets.

In the preliminary determination, the Department denied Linz's claim for a small quantity surcharge. Linz stated in its January 6, 1997 supplemental response that the application of its small quantity price adjustment is "flexible, made on a case-by-case basis, and is meant only as a guideline." Therefore, Linz was unable to demonstrate, based on the information on the record, the required consistency.

Prior to verification, Linz provided additional information on its small quantity surcharge. The company stated that while its small quantity adjustment policy was meant to be a guideline and to be flexible, it was to be followed in all possible cases and was to be applied to virtually all small quantity sales. Linz stated that, during the POI, it followed the small quantity price increases in all cases but eleven. The company stated that there were specific reasons why there were eleven exceptions to this policy during the POI.

For purposes of this final determination, we again examined Linz's home market sales to determine whether or not price increases were applied when appropriate, and to determine whether or not price increases were applied consistently in accordance with Linz's 1992 internal memorandum on low volume sales. An examination of Linz's home market prices during the POI demonstrated that Linz did not consistently adhere to its small quantity add-on pricing policy with respect to the four quantity brackets listed in its 1992 sales memorandum, even disregarding the eleven sales which Linz stated were exceptions to this pricing policy. Therefore, we do not find that there was a clear and direct correlation between price and quantity. Thus, the company

did not meet the requirements of section 353.55(b) of the regulations and we have not granted their claimed differences due to small quantity surcharges.

Comment 7: Sales of Comparable Quantities

Linz argues that absent an adjustment to normal value for quantity discounts under section 353.55(b) of the regulations, the Department should resort to comparisons of only sales in comparable quantities in the two markets. Linz states that under 19 C.F.R. 353.55(a), "in comparing the United States price with foreign market value, the Secretary normally will use sales of comparable quantities of merchandise." Linz states that all sales in both the U.S. and home market over a certain amount are treated equally in terms of quantity pricing adjustments. Thus, the Department should only use home market sales over that amount in calculating normal value.

Petitioner states that the Department should reject Linz's arguments for comparable quantities. Petitioner states that in defining its notion of comparable quantities, Linz has classified all sales into one of two quantity ranges, and that these comparable quantity ranges are flawed for two reasons. First, they contradict the five quantity ranges that Linz has claimed in the context of the quantity discount. Thus, Linz is arguing for one set of quantity ranges with respect to quantity discounts, and a different set of quantity ranges with respect to comparable quantities. Second, Linz has created an overly-broad upper range.

DOC Position: The issue of comparison of comparable quantities arose in Notice of Final Determination of Sales at Less Than Fair Value: Extruded PVC and Polystyrene Framing Stock from the United Kingdom (*Framing Stock*), 61 FR 51412 (October 2, 1996). In *Framing Stock*, we stated that information on the record demonstrated that the prices between different quantity bands were sufficiently distinct to warrant comparisons at comparable quantity bands. In the instant investigation, we reviewed the pricing information on home market sales between sales over a certain quantity and those below that quantity to determine whether the prices between these two quantity bands were sufficiently distinct to also warrant comparisons at comparable quantities. Based upon our pricing analysis, we found that the pricing between the two quantity bands was not sufficiently distinct to warrant comparisons at comparable quantity bands. Therefore, we based normal value on the weighted-

average of all comparable sales, regardless of quantity.

Comment 8: Calculation of Financial Expenses

Petitioner states that the Department should continue to include only short-term interest income as an offset to interest expense. Petitioner notes that, in the preliminary determination, the Department adjusted Linz's reported interest income to approximate the portion of interest income attributable to short-term assets. However, as a result of verification, petitioner concludes that the Department now has the data to accurately determine which items of interest income are short-term and which are long-term. Linz states that petitioner, in its brief, did not specifically state which amount of Linz's interest income is short-term and long-term. As a result, Linz argues that the Department should disregard petitioner's request for an adjustment to the calculation of Linz's interest expense.

DOC Position: We agree with petitioner. During verification, the Department verified the portion of interest income related to short-term investments of its working capital. For the final determination, the Department adjusted Linz's reported net interest expense rate to include only short-term interest income as an offset to interest expense.

Comment 9: Parent Company G&A

The petitioner claims that Linz understated its general and administrative expenses by failing to account for expenses incurred by its non-operating corporate parent. Petitioner argues that because the section D questionnaire instructed Linz to include in its reported G&A an amount for administrative services performed by its parent, the Department should increase Linz's reported G&A expenses to include a G&A expense amount incurred by its parent company. Linz asserts that the Department has already included the expenses of Linz's parent company in its calculation of the G&A expense.

DOC Position: The Department's practice is to include a portion of parent company G&A expenses where appropriate. In this case, Linz's reported G&A expense already reflects expenses incurred on its behalf by its parent. Therefore, to include additional G&A amounts as argued by petitioner would overstate G&A.

Borckenstein

Comment 10: Affiliation Due To Close Supplier Relationship

Petitioner claims that information on the record indicates a close supplier relationship between Borckenstein and its sole U.S. customer of the subject merchandise, Beavertown, and thus Borckenstein and the U.S. customer would fall within the definition of affiliated parties set forth in section 771(33) of the Act. Petitioner contends that a determination of affiliation may be based on a close supplier relationship for the following reasons. By purchasing a large percentage of a supplier's subject sales, the buyer could extract price and other concessions from the supplier by threatening to purchase the products from another vendor. Because such an action would severely impact the business of the supplier, the purchasing company is in a position to control the related supplier by exerting restraint or direction over the supplier. Therefore, petitioner argues that Borckenstein and Beavertown are affiliated and that Borckenstein's U.S. sales should be classified as CEP sales.

Borckenstein states that it is not affiliated with Beavertown and that there is no close supplier relationship based upon the percentage of Beavertown's purchases compared to Borckenstein's total sales revenue. Borckenstein argues that petitioner's assertion that this percentage should only be based on subject sales and not on subject and non-subject sales is flatly contrary to current Department practice. Borckenstein states that the Department's standard practice of determining close supplier relationship is based on the percentage of "total annual sales," not solely the percentage of subject sales. See Notice of Final Determination of Sales at Less Than Fair Value: Large Newspaper Printing Presses and Components Thereof, Whether Assembled or Unassembled from Japan, (hereinafter *Printing Presses*) 61 FR 38139, (July 23, 1996).

DOC Position: We disagree with the petitioner's claim that information on the record indicates that a close supplier relationship exists between Borckenstein and its sole U.S. customer of subject merchandise. We examined this issue at verification and did not find evidence of a close supplier relationship. In addition, the Department has dealt with a similar issue in other recent cases and likewise did not find affiliation. See, e.g., *Printing Presses*.

In *Printing Presses*, the Department indicated, among other factors, that close supplier relationships may occur

when a majority of a supplier's sales are made to one customer. However, in the instant case, Borckenstein's financial records indicate that Beavertown's purchases account for only a small portion of Borckenstein's total sales revenue, which is based on sales of the subject merchandise and closely related products. Therefore, Borckenstein is not reliant on Beavertown, and we find no close supplier relationship in this case. Thus, the two parties are not affiliated under 771(33) of the Act.

Comment 11: Quantity Discount Under Section 353.55(b)

Borckenstein states that the information on the record supports an adjustment for differences in quantities sold in the U.S. and Austrian markets pursuant to section 773(a)(6) of the Act and section 353.55(b) of the Department's regulations. The claim for the quantity adjustment is based on raw material rebates received from Borckenstein's raw material supplier, and the additional cost of machine recalibrations in the home market. Petitioner states that Borckenstein has failed to demonstrate a clear and direct correlation between price differences and quantities sold, or price differences and costs incurred. Therefore, Borckenstein's claimed quantity adjustment pursuant to section 353.55(b) must be denied.

DOC Position: We agree with the petitioner. The criteria for recognizing quantity discounts pursuant to 19 CFR 353.55(b) have been fully explained in the Department's Position to *Comment 6*. Borckenstein has not demonstrated a clear and direct correlation between price differences and quantities sold or costs incurred. See the discussion of Brass Sheet and Strip referenced in *Comment 6*. Furthermore, although Borckenstein contends that the additional cost of machine recalibrations are appropriate costs on which to base a difference in quantities adjustment, however, it is the Department's practice not to allow a quantity based adjustment under 19 CFR 353.55(b) based upon the additional setup time that is required for shorter runs. The Department will grant cost adjustment claims based on direct manufacturing costs; recalibration of machinery does not constitute a direct cost. In addition, the claim for the rebate of raw material does not meet the standard set forth in Brass Sheet and Strip for an adjustment under 353.55(b). It is our practice to use one average cost for a raw material; different costs cannot be attributed to the same raw material. Therefore, Borckenstein is unable to demonstrate that price differences are

attributable to the production of different quantities. Accordingly, the Department has not granted Borckenstein's claim for a quantity discount.

Comment 12: Raw Material Rebate

Petitioner argues that the Department should not grant an adjustment for a raw material rebate that Borckenstein receives from its supplier and that Borckenstein claims it used to produce subject merchandise destined for the U.S. market. Petitioner states that the granting of an export-based rebate on raw material purchases is commonly referred to as "input dumping," and the Department has condemned input dumping in past cases, and must continue to do so in the present case. Borckenstein contends that the Department should adjust for its claimed raw material rebate. Borckenstein argues that the rebate is not directed at the U.S. market but to the customer who purchases large quantities of product which allows Borckenstein to achieve economies of scale in production. Borckenstein also asserts that petitioner is incorrect when it stated that there is input dumping in this case.

DOC Position: Section 773(a)(4)(B) of the Act authorizes the Department to adjust for "differences in circumstances of sales," which include such things as differences in commissions, credit terms, guarantees, warranties, technical assistance, and servicing. We note that while the regulations do provide for adjustments to production cost differences in two instances (where quantity discounts reflect savings in production of different quantities (19 CFR 353.55(b)(2)), and where differences in production cost are due to differences in physical characteristics (19 CFR 353.57(b)), neither of these provisions is applicable here. Since the type of adjustment at issue here does not relate to physical differences in merchandise, it is not an allowable adjustment under the difference-in-merchandise provision. In addition, in view of the fact that the proposed adjustment cannot be deemed a sales-related expense, it is not appropriate to adjust for the rebate as a circumstance of sale.

Comment 13: Raw Material Costs

The petitioner asserts that Borckenstein's costs of production for home market sales is underreported. Petitioner states that Borckenstein received a rebate on raw material only for finished yarn exported to the United States. Since this rebate did not apply to home market sales, this rebate should

not be attributable to raw material costs for COP applied to home market sales. Thus, the actual fiber costs incurred by Borckenstein for home market sales are higher than have been reported. Borckenstein states that the raw material costs reported by Borckenstein are weighted-average costs between the home market and the U.S. market, consistent with standard Department methodology. In addition, Borckenstein states that the Department verified the accuracy of Borckenstein's reported material cost at verification and found no discrepancies.

DOC Position: We agree with Borckenstein that the Department's normal practice is to compute a single weighted-average COP for each unique model subject to the investigation. Accordingly, we did not adjust Borckenstein's reported raw material cost for the final determination.

Comment 14: Treatment of Commission as a Rebate

The petitioner asserts that Beavertown Mills, Borckenstein's sole U.S. customer of subject merchandise, is wholly-owned by Titan Textile Co., and that Borckenstein's commission agent is also wholly-owned by Titan Textile Co. Thus, petitioner asserts that the reported commission payments are in effect payments to the customer itself. According to petitioner, the amount paid to the customer cannot be considered a commission, but is instead a rebate. Therefore, the Department should continue to treat the claimed commission as a rebate. Borckenstein contends that the payment is made to its selling agent, therefore, the payment should be considered a commission, not a rebate. Borckenstein contends that the selling agent never takes possession of the merchandise, nor does it pay the selling agent directly for the merchandise. In addition, Borckenstein states that these payments of commissions are accounted for in its books as commissions, and are invoiced to its selling agent as commissions.

DOC Position: In the preliminary determination, the Department treated Borckenstein's U.S. commissions as rebates based on its understanding that the commission agent was wholly-owned by Beavertown's parent company. Because the commission was treated as a rebate there was no offset for indirect selling expenses in the preliminary determination. At verification, we learned that Borckenstein uses selling agents for all of its U.S. sales. The Department established that the selling agent used for sales of the subject merchandise performed the functions of a

commission agent. We verified that the U.S. customer, not the selling agent, pays Borckenstein for the merchandise. In addition, Borckenstein makes payments directly to the selling agent for services rendered in the sales transaction.

During verification, we also reviewed documentation regarding the shareholder listings for Borckenstein's selling agent, Beavertown, and Beavertown's parent company which demonstrated that the selling agent is not affiliated with Beavertown. The controlling shareholder of the selling agent owns no shares in either Beavertown or Beavertown's parent company. Therefore, we do not find Borckenstein's selling agent to be affiliated with Beavertown under section 771(33) of the Act for the purposes of the treatment of this commission. Therefore, in this final determination, we have treated this expense as a commission and offset it with home market indirect selling expenses.

Comment 15: Depreciation Expense in Reported Cost of Production

The petitioner contends that Borckenstein underreported its depreciation expense. Among the excluded costs were depreciation expenses for the plant in which the product is produced, all depreciation related to the general and administrative functions of the company, and depreciation related to assets that directly or indirectly support the manufacturing operation. Borckenstein states that it does not object to an appropriate and reasonable increase of submitted depreciation expenses in calculating the cost of production.

DOC Position: We agree with petitioner. For the final determination, we recalculated depreciation expense to include depreciation from the other categories of fixed assets used in the production of the subject merchandise. Additionally, we included a portion of the depreciation expense related to Borckenstein's assets used to perform the administrative functions of the company.

Comment 16: Failure to Include Indirect Material Expenses

The petitioner contends that Borckenstein failed to include indirect material expenses in its reported cost of production. The indirect materials excluded were: (1) Materials purchased for the refurbishment of the open-end equipment specifically used to produce the merchandise under investigation; and (2) repair materials. Further, the petitioner asserts that these costs were

incurred during the fiscal period on which Borckenstein's cost response was based, and related directly to the equipment used to produce the merchandise under investigation. Borckenstein states that it properly reported indirect material expenses in its reported cost of production, and that, at verification, the Department determined that the expenses in question were not incurred for the production of the subject merchandise during the POI.

DOC Position: The Department agrees, in part, with petitioner. The Department verified that the majority of the parts purchased by respondent in the last month of the cost calculation period were used to refurbish and extend the useful life of the machinery sold subsequent to the POI. Given the fact that Borckenstein intended to sell the machinery, the company expensed the cost of these parts rather than capitalize them. In the normal course of business, Borckenstein depreciates its machinery over four years. Since the refurbishment was so extensive, we agree that the costs incurred should have been capitalized. Accordingly, we consider it appropriate for Borckenstein to depreciate the refurbishment costs over four years beginning with the month of purchases (the last month of the POI). Thus, Borckenstein should recognize one month of depreciation related to the purchased parts in its submitted POI costs of manufacturing. We verified that the remaining parts Borckenstein purchased at the end of the year related to repairs and maintenance for the subsequent year. In the ordinary course of business, Borckenstein expenses small parts and maintenance supplies when purchased rather than when consumed. As such, the Department maintains that the cost of these parts are representative of Borckenstein's yearly repairs and maintenance expense and should be included in its COP and CV. However, consistent with 19 C.F.R. § 353.59(a), which permits the Department to disregard insignificant adjustments, we have elected not to adjust Borckenstein's COM for either the depreciation expense or cost of the parts, since the addition of these costs would not affect our overall margin calculation.

Continuation of Suspension of Liquidation

In accordance with section 735(c) of the Act, we are directing the Customs Service to continue to suspend liquidation of all entries of open-end spun rayon singles yarn that are entered, or withdrawn from warehouse, for consumption on or after March 26,

1997, the date of publication of our preliminary determination in the **Federal Register**. We will instruct the Customs Service to require a cash deposit or the posting of a bond equal to the weighted-average amount by which the normal value exceeds the export price, as indicated in the chart below. This suspension of liquidation will remain in effect until further notice.

Exporter/manufacturer	Weighted average margin percentage
Linz	12.36
Borckenstein	2.36
All Others	7.42

Pursuant to section 733(d)(1)(A) and section 735(c)(5) of the Act, the Department has not included zero or *de minimis* weighted-average dumping margins, or margins determined entirely under section 776 of the Act, in the calculation of the "all others" rate.

ITC Notification

In accordance with section 735(d) of the Act, we have notified the ITC of our determination. As our final determination is affirmative, the ITC will determine, within 45 days, whether these imports are causing material injury, or threat of material injury, to an industry in the United States. If the ITC determines that material injury, or threat of material injury, does not exist, the proceeding will be terminated and all securities posted will be refunded or canceled. If the ITC determines that such injury does exist, the Department will issue an antidumping duty order directing Customs officials to assess antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

This determination is published pursuant to section 735(d) of the Act.

Dated: August 8, 1997.

Richard W. Moreland,

Acting Assistant Secretary for Import Administration.

[FR Doc. 97-21710 Filed 8-14-97; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

Applications for Duty-Free Entry of Scientific Instruments

Pursuant to Section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub.

L. 89-651; 80 Stat. 897; 15 CFR part 301), we invite comments on the question of whether instruments of equivalent scientific value, for the purposes for which the instruments shown below are intended to be used, are being manufactured in the United States.

Comments must comply with 15 CFR 301.5(a) (3) and (4) of the regulations and be filed within 20 days with the Statutory Import Programs Staff, U.S. Department of Commerce, Washington, D.C. 20230. Applications may be examined between 8:30 A.M. and 5:00 P.M. in Room 4211, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C.

Docket Number: 97-060. **Applicant:** The Pennsylvania State University, Chemistry Department, 152 Davey Laboratory, University Park, PA 16802. **Instrument:** NMR Spectrometer, Model Avance DRX-600. **Manufacturer:** Bruker Instruments, Inc., Switzerland. **Intended Use:** The instrument will be used for studies of proteins and nucleic acids produced in the research laboratories of the chemistry and the biochemistry and molecular biology departments. The experiments are all state-of-the-art nuclear magnetic resonance experiments. Most will be in aqueous solution and involve multiple nuclei: ^1H , ^2H , ^{15}N , ^{13}C , and ^{31}P . **Application accepted by Commissioner of Customs:** July 15, 1997.

Docket Number: 97-062. **Applicant:** Clemson University, Department of Bioengineering, 501 Rhodes Engineering Research Center, P.O. Box 340905, Clemson, SC 29634-0905. **Instrument:** Knee Joint Simulator. **Manufacturer:** UCL Ltd., United Kingdom. **Intended Use:** The instrument will be used for a research program conducted to provide materials and designs for artificial joints that can last longer than those presently used. The relevant research projects will include but are not limited to the following:

- (1) Reciprocating-Sliding Wear Resistance of Orthopaedic Titanium Alloys,
- (2) Ultrasonic Method for *In-situ* Continuous Wear Measurements of Orthopaedic Alloys,
- (3) Analytical Modeling of Total Knee Replacement: Effect of Misalignment,
- (4) Elastomeric Composites as Bearing Surfaces, and
- (5) Improving Boundary Lubrication of Elastomeric Bearing Surfaces.

In addition, the instrument will be used for educational purposes in various bioengineering courses. **Application accepted by Commissioner of Customs:** July 16, 1997.

Docket Number: 97-064. **Applicant:** University of Illinois at Urbana-Champaign, Purchasing Division, 506 South Wright Street, 207 Henry Administration Building, Urbana, IL 61801. **Instrument:** Reflection High Energy Electron Gun. **Manufacturer:** Focus GmbH, Germany. **Intended Use:** The instrument will be used for a variety of studies on the mechanisms of growth of thin films. In particular, there will be studies of magnetic multilayer materials; of the effect of surface steps on films growth and of a technique called convergent beam diffraction. This instrument allows both real time monitoring of the growth conditions and quick and reliable post-growth quality control of the films' crystallinity prior to further study via transfer into a separate low-energy electron microscope to perform further microscopic studies without the necessity of breaking vacuum. **Application accepted by Commissioner of Customs:** July 17, 1997.

Docket Number: 97-065. **Applicant:** Princeton University, P.O. Box 33, Princeton, NJ 08544-0033. **Instrument:** (50) Seismometers. **Manufacturer:** Guralp Systems Ltd., United Kingdom. **Intended Use:** The instruments will be used to study earthquakes and the interior structure of the earth in a newly devised high school science curriculum, in which students study seismicity and try to answer fundamental geophysical questions about the earth. **Application accepted by Commissioner of Customs:** July 17, 1997.

Docket Number: 97-066. **Applicant:** University of California, San Diego, Scripps Institution of Oceanography, 7835 Trade Street, San Diego, CA 92121. **Instrument:** Wave Measurement Equipment. **Manufacturer:** Datwell bv, The Netherlands. **Intended Use:** The instruments will be used in support of ongoing and proposed research on the evolution of directional wave spectra across the continental shelf and near complex bathymetric features. The instrument will significantly expand Department of Defense wave data measurement capabilities on the shelf and will be used over the next 5 years by a consortium of Office of Naval Research principal investigators studying wave propagation processes in a wide range of geographic settings. **Application accepted by Commissioner of Customs:** July 22, 1997.

Docket Number: 97-067. **Applicant:** Princeton University, P.O. Box 33, Princeton, NJ 08544-0033. **Instrument:** EPR Spectrometer, Model E580 FT/CW. **Manufacturer:** Bruker Instruments, Germany. **Intended Use:** The instrument

will be used for studies of sample paramagnetic materials obtained from various sources including chemical synthesis and natural products. The research projects will include the following:

- (1) Structure and function of multi-nuclear metallo-enzymes,
- (2) Molecular probes of the mechanism of cytochrome,
- (3) ENDOR studies of metalloproteins,
- (4) Observing and exploiting intermolecular multiple-quantum coherences in solution ESR,
- (5) EPR analysis of photoluminescent porous silicon,
- (6) Core transformation in iron-sulfur clusters,
- (7) Pulsed EPR studies of vanadium partial oxidation catalysts and,
- (8) Dynamics of cation diffusion to ionomers.

In addition, the instrument will be used for educational purposes in the course "Electron Magnetic Resonance Spectroscopies: Survey of Techniques, Applications and Spectral Interpretation." **Application accepted by Commissioner of Customs:** July 28, 1997.

Frank W. Creel,

Director, Statutory Import Programs Staff.
[FR Doc. 97-21712 Filed 8-14-97; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

University of Vermont, et al.; Notice of Consolidated Decision on Applications for Duty-Free Entry of Scientific Instruments

This is a decision consolidated pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 A.M. and 5:00 P.M. in Room 4211, U.S. Department of Commerce, 14th and Constitution Avenue, N.W., Washington, D.C.

Comments: None received. Decision: Approved. No instrument of equivalent scientific value to the foreign instruments described below, for such purposes as each is intended to be used, is being manufactured in the United States.

Docket Number: 96-149R. **Applicant:** University of Vermont, Burlington, VT 05405-0068. **Instrument:** Motion Analysis System and Telemg System, Model Elite Plus. **Manufacturer:** Bioengineering Technology & Systems, Italy. **Intended Use:** See notice at 62 FR

6216, February 11, 1997. *Reasons:* The foreign instrument provides systematic triggering of kinematic data acquisition for reliability and recording of movement events with durations as short as 40 ms. *Advice received from:* National Institutes of Health, June 26, 1997.

Docket Number: 97-039. *Applicant:* University of California, San Diego, San Diego, CA 92121. *Instrument:* Wave Measurement Equipment. *Manufacturer:* Datawell bv, The Netherlands. *Intended Use:* See notice at 62 FR 32766, June 17, 1997. *Reasons:* The foreign instrument provides: (1) more reliable wave direction estimates at frequencies under 1.0 Hz and over 3.0 Hz with less variability within the range, and (2) better wave spread estimates than comparable domestic equipment. *Advice received from:* Two domestic manufacturers of similar equipment, April 23, 1997 (comparable case).

Docket Number: 97-047. *Applicant:* Emory University, Atlanta, GA 30322. *Instrument:* Slice Physiology Setup, Model 240. *Manufacturer:* Luigs and Neumann, Germany. *Intended Use:* See notice at 62 FR 34691, June 27, 1997. *Reasons:* The foreign instrument provides positioning of a group of microelectrodes for single-cell neuronal recording under an optical microscope with placement precision of 0.1 μ m. *Advice received from:* National Institutes of Health, June 26, 1997.

Docket Number: 97-049. *Applicant:* California State Polytechnic University, Pomona, CA 91768. *Instrument:* Stopped-Flow Spectrometer, Model SX.18MV. *Manufacturer:* Applied Photophysics Ltd., United Kingdom. *Intended Use:* See notice at 62 FR 36261, July 7, 1997. *Reasons:* The foreign instrument provides: (1) sequential mixing capability, (2) dead time of 1.3 ms, and (3) a cell volume of 20 μ l with a flow circuit volume of 100 μ l. *Advice received from:* National Institutes of Health, June 26, 1997.

Docket Number: 97-050. *Applicant:* University of Pennsylvania, Philadelphia, PA 19104. *Instrument:* Mass Spectrometer, Model AutoSpec. *Manufacturer:* Micromass, United Kingdom. *Intended Use:* See notice at 62 FR 36261, July 7, 1997. *Reasons:* The foreign instrument provides a high resolution double focussing magnetic sector analyzer with 3-sector geometry. *Advice received from:* National Institutes of Health, June 26, 1997.

The National Institutes of Health and two domestic manufacturers of similar equipment advise that (1) the capabilities of each of the foreign instruments described above are

pertinent to each applicant's intended purpose and (2) they know of no domestic instrument or apparatus of equivalent scientific value for the intended use of each instrument.

We know of no other instrument or apparatus being manufactured in the United States which is of equivalent scientific value to any of the foreign instruments.

Frank W. Creel,

Director, Statutory Import Programs Staff.
[FR Doc. 97-21711 Filed 8-14-97; 8:45 am]
BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 080697F]

Gulf of Mexico Fishery Management Council; Public Meetings

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 public meetings.

DATES: The meetings will be held on September 8-11, 1997.

ADDRESSES: These meetings will be held at the Adam's Mark Hotel, 64 South Water Street, Mobile, AL; telephone: 334-438-4000.

Council address: Gulf of Mexico Fishery Management Council, 3018 U.S. Highway 301 North, Suite 1000, Tampa, FL 33619.

FOR FURTHER INFORMATION CONTACT: Wayne E. Swingle, Executive Director; telephone: (813) 228-2815.

SUPPLEMENTARY INFORMATION:

Council

September 10

8:30 a.m.—Convene.

8:45 a.m. - 10:15 a.m.—Hear presentation on Marine Fisheries Reserves.

10:15 a.m. - 11:00 a.m.—Hear presentation on Use of Satellite Transponders.

1:00 p.m. - 1:30 p.m.—Hear presentation on NOAA Enforcement Policy.

1:30 p.m. - 3:30 p.m.—Receive a report of the Mackerel Management Committee.

3:30 p.m. - 5:30 p.m.—Receive a report of the Reef Fish Management Committee.

September 11 8:30 a.m. - 8:45 a.m.—Receive a report of the Data Collection Committee.

8:45 a.m. - 9:00 a.m.—Receive a report of the Coral Management Committee.

9:00 a.m. - 9:15 a.m.—Receive a report of the Habitat Protection Management Committee.

9:15 a.m. - 9:30 a.m.—Receive a report on the Structure of the Socioeconomic Panel.

9:30 a.m. - 9:45 a.m.—Receive a report of the Highly Migratory Species Billfish Advisory Panel Meeting.

9:45 a.m. - 10:00 a.m.—Receive a report of the Highly Migratory Species Longline Advisory Panel Meeting.

10:00 a.m. - 10:15 a.m.—Receive a report of the U.S. Coast Guard Enforcement Meeting.

10:15 a.m. - 10:30 a.m.—Receive a report on the South Atlantic Fishery Management Council Liaison.

10:30 a.m. - 10:45 a.m.—Receive Enforcement Reports.

10:45 a.m. - 11:15 a.m.—Receive Director's Reports.

11:15 a.m. - 11:30 a.m.—Other business to be discussed.

Committees

11:30 a.m. - 11:45 a.m.—Hold Chairmen's Election.

September 8

11:00 a.m. - 12:00 noon—Hold Orientation Session for new Council members.

1:00 p.m. - 5:30 p.m.—Convene the Mackerel Management Committee to review Draft Amendment 9/Regulatory Impact Review (RIR) and an options paper for Draft Amendment 10.

September 9

8:00 a.m. - 9:00 a.m.—Convene the Coral Management Committee to review an issue related to losses of cultured live rock due to red tide.

9:00 a.m. - 10:30 a.m.—Convene the Habitat Protection Committee to review the status of a generic amendment to Gulf Fishery Management Plans (FMPs) addressing essential fisheries habitat (EFH) and selection of technical review panel for EFH amendment.

10:30 a.m. - 11:30 a.m.—Convene the Data Collection Committee to review the Recreational and Commercial Fisheries Initiative programs.

1:00 p.m. - 5:30 p.m.—Convene the Reef Fish Management Committee to review Draft Amendment 16/RIR, a schedule for preparation of Draft Amendment 17, a summary of the Red Snapper Peer Group reviews, and an updated projection of recreational landings of red snapper for 1997. The Committee will also select public hearing locations for Draft Amendment 16.

Special Accommodations

These meetings are 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 August 29, 1997.

Dated: August 11, 1997.

Gary C. Matlock,

*Director, Office of Sustainable Fisheries,
National Marine Fisheries Service.*

[FR Doc. 97-21665 Filed 8-14-97; 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
Pakistan**

August 11, 1997.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs increasing limits.

EFFECTIVE DATE: August 18, 1997.

FOR FURTHER INFORMATION CONTACT: Ross Arnold, 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 limits for certain categories are being increased, variously, for carryover and recrediting of unused carryforward.

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 61 FR 66263, published on December 17, 1996). Also see 61 FR 68245, published on December 27, 1996.

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

August 11, 1997.

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 December 20, 1996, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton and man-made fiber textile products, produced or manufactured in Pakistan and exported during the twelve-month period which began on January 1, 1997 and extends through December 31, 1997.

Effective on August 18, 1997, you are directed to increase the limits the following categories, as provided for under the Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles and Clothing:

Category	Adjusted limit ¹
219	8,256,340 square meters.
226/313	121,600,260 square meters.
237	401,558 dozen.
239	1,890,536 kilograms.
314	6,004,610 square meters.
315	80,931,186 square meters.
317/617	32,267,768 square meters.
331/631	2,159,709 dozen pairs.
335/635	366,281 dozen.
339	1,168,372 dozen.
340/640	631,013 dozen of which not more than 217,058 dozen shall be in Category 340-D/640-D ² .
341/641	722,805 dozen.
342/642	357,751 dozen.
359-C/659-C ³	1,445,610 kilograms.
360	4,649,160 numbers.
361	6,000,660 numbers.
369-F/369-P ⁴	2,219,916 kilograms.
369-S ⁵	650,774 kilograms.
613/614	24,077,967 square meters.
615	25,614,854 square meters.

Category	Adjusted limit ¹
625/626/627/628/629	78,779,850 square meters of which not more than 35,486,420 square meters shall be in Category 625; not more than 35,486,420 square meters shall be in Category 626; not more than 35,486,420 square meters shall be in Category 627; not more than 7,342,018 square meters shall be in Category 628; and not more than 35,486,420 square meters shall be in Category 629.
647/648	868,060 dozen.
666-P ⁶	732,470 kilograms.
666-S ⁷	4,235,760 kilograms.

¹The limits have not been adjusted to account for any imports exported after December 31, 1996.

²Category 340-D: only HTS numbers 6205.20.2015, 6205.20.2020, 6205.20.2025 and 6205.20.2030; Category 640-D: only HTS numbers 6205.30.2010, 6205.30.2020, 6205.30.2030, 6205.30.2040, 6205.90.3030 and 6205.90.4030.

³Category 359-C: only HTS numbers 6103.42.2025, 6103.49.8034, 6104.62.1020, 6104.69.8010, 6114.20.0048, 6114.20.0052, 6203.42.2010, 6203.42.2090, 6204.62.2010, 6211.32.0010, 6211.32.0025 and 6211.42.0010; Category 659-C: only HTS numbers 6103.23.0055, 6103.43.2020, 6103.43.2025, 6103.49.2000, 6103.49.8038, 6104.63.1020, 6104.63.1030, 6104.69.1000, 6104.69.8014, 6114.30.3044, 6114.30.3054, 6203.43.2010, 6203.43.2090, 6203.49.1010, 6203.49.1090, 6204.63.1510, 6204.69.1010, 6210.10.9010, 6211.33.0010, 6211.33.0017 and 6211.43.0010.

⁴Category 369-F: only HTS number 6302.91.0045; Category 369-P: only HTS numbers 6302.60.0010 and 6302.91.0005.

⁵Category 369-S: only HTS number 6307.10.2005.

⁶Category 666-P: only HTS numbers 6302.22.1010, 6302.22.1020, 6302.22.2010, 6302.32.1010, 6302.32.1020, 6302.32.2010 and 6302.32.2020.

⁷Category 666-S: only HTS numbers 6302.22.1030, 6302.22.1040, 6302.22.2020, 6302.32.1030, 6302.32.1040, 6302.32.2030 and 6302.32.2040.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to 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. 97-21648 Filed 8-14-97; 8:45 am]

BILLING CODE 3510-DR-F

DEPARTMENT OF DEFENSE**Department of the Air Force****[(AFROTC) Form 20]****Request Renewal of the Air Force Reserve Officer Training Corps**

AGENCY: Cadet Personnel Division, Air Force Reserve Officer Training Corps (AFROTC).

ACTION: Notice.

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Cadet Personnel Division, Air Force Reserve Officer Training Corps, announces the proposed reinstatement of a public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by October 14, 1997.

ADDRESSES: Written comments and recommendations on the proposed information collection should be sent to HQ AFROTC/RRFP, 551 East Maxwell Blvd, Maxwell Air Force Base, AL 36112-6106.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection to obtain a copy of the proposal and associated collection instruments, please write the above address or call (334) 953-7841.

Title, Associated Form, and OMB Number: Air Force Reserve Officer Training Form 20, "Application for AFROTC Membership," OMB Number 0701-0105.

Needs and Uses: To obtain the information needed by HQ AFROTC and the AFROTC Detachment on which to base a decision of acceptance/nonacceptance to be a member of Air Force ROTC.

Affected Public: Individuals.

Annual Burden of Hours: 4,000.

Number of Respondents: 12,000.

Responses Per Respondent: 1.

Average Burden Per Response: 20 minutes.

Frequency: Once.

SUPPLEMENTARY INFORMATION:**Summary of Information Collection**

Respondents are high school and college students who are requesting membership in the Air Force ROTC program. Information gathered on the form is used to determine eligibility to enter Air Force ROTC. All information collected is used to establish the individuals personnel record, upon acceptance. Additionally, certain information collected on the form is used to determine an individuals status once accepted. Also, information gathered will help specifically determine an individuals acceptance/nonacceptance. If this information is not collected a determination of eligibility cannot be made.

Barbara A. Carmichael,

Alternate Air Force Federal Register Liaison Officer.

[FR Doc. 97-21630 Filed 8-14-97; 8:45 am]

BILLING CODE 3910-01-P

DEPARTMENT OF DEFENSE**Corps of Engineers, Department of the Army****Deauthorization of Water Resources Projects**

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

ACTION: Changes to conditions for project deauthorization; deauthorization of selected projects; and correction of project deauthorization list.

SUMMARY: The Corps of Engineers is publishing notice of (1) changes to conditions for project deauthorization, enacted in the Water Resources Development Act of 1996, Pub. L. 104-303; (2) the deauthorization of the Burlington Dam, North Dakota, project and the Lake Darling pool raise unit of the Souris River, North Dakota, project; and (3) a second correction to the list of "Projects Deauthorized on November 29, 1995, by Section 1001(a) of Pub. L. 99-662."

FOR FURTHER INFORMATION CONTACT: Mr. John A. Micik, Headquarters, U.S. Army Corps of Engineers, Attention: CECW-BA, Washington, D.C. 20314-1000. Tel. (202) 761-0705.

SUPPLEMENTARY INFORMATION:**Conditions for Project Deauthorization**

Section 228 of the Water Resources Development Act of 1996, Pub. L. 104-303, dated October 12, 1996, changes the conditions for project deauthorization.

Projects and separable elements of projects will be biennially reported to Congress as eligible for deauthorization after 7 full fiscal years have passed without Federal funds having been obligated. Section 1001(b)(2) of the Water Resources Development Act of 1986, Pub. L. 99-662, 33 U.S.C. 579a(b)(2), originally specified 10 full fiscal years. The five-year sunset provision of § 1001(a), Pub. L. 99-662, 33 U.S.C. 579a(a), is no longer in effect.

The statutory notifications of affected U.S. Senators and Members of the U.S. House of Representatives will be made upon transmittal of the biennial eligibility list to the President of the Senate and the Speaker of the House. Section 1001(b)(2), Pub. L. 99-662, originally required notifications before transmittal of the eligibility list. The change allows the notifications to specify the calendar date when the listed projects will be deauthorized, which is 30 months from the transmittal date.

Project deauthorization eligibility under § 1001(b)(2), Pub. L. 99-662, as amended, includes projects authorized for preconstruction planning, engineering and design only. Previously, only projects fully authorized for construction fell within the purview of § 1001(b)(2). The change does not affect the deauthorization of water resources studies under the provisions of § 710, Pub. L. 99-662, 33 U.S.C. 2264.

Deauthorizations

Section 1124 of Pub. L. 99-662 provided for the automatic deauthorization of the Burlington Dam, North Dakota, project, and the Lake Darling pool raise unit of the Souris River, North Dakota, project upon completion of the Rafferty and Alameda reservoir projects in Canada. The projects were cooperative efforts between the United States and Canada. The Rafferty and Alameda projects were certified as complete and 100 percent operable on March 10, 1995; therefore, the Burlington Dam, North Dakota, project and the Lake Darling pool raise unit of the Souris River, North Dakota, project were deauthorized on March 10, 1995.

Corrected List

On the list of "Projects Deauthorized on November 29, 1995, by Section 1001(a) of Pub. L. 99-662 (Corrected List)," published in the **Federal Register** on January 22, 1997, (Vol. 62, No. 14, 3271), the East Fork of Trinity River, Texas, project should not have been listed since planning funds were obligated on the project prior to

November 29, 1995. A corrected list is provided.

Dated: July 29, 1997.

John H. Zirschky,

Acting Assistant Secretary of the Army (Civil Works).

Projects Deauthorized on November 29, 1995 by Section 1001(A) of Public Law 99-662—Corrected List

Corrects the list published in the **Federal Register** on January 22, 1997 (Vol. 62, No. 14, 3271).

District	Project name	Primary state	Purpose
SWL	MUD CREEK WETLANDS	AR	FC
SPK	PAJARO RIVER, SANTA CRUZ *	CA	FC
SPN	SANTA CRUZ HARBOR, EAST JETTY *	CA	N
SPA	BELEN	NM	FC
NAN	LAKE GEORGE	NY	FC
GLB	CONNEAUT SMALL BOAT HARBOR *	OH	N
GLB	FAIRPORT HARBOR DREDGING *	OH	N
GLB	FAIRPORT SMALL BOAT HARBOR *	OH	N
MVM	MEMPHIS HARBOR *	TN	N

*Projects reauthorized in 1990. See FEDERAL REGISTER notice of September 9, 1994 (Vol. 59, No. 174, 46624–46625).

Total: 9.

KEY TO ABBREVIATIONS:

GLB Buffalo District.

MVM Memphis District.

NAN New York District.

SPA Albuquerque District.

SPK Sacramento District.

SPN San Francisco District.

SWL Little Rock District.

FC Flood Control.

N Navigation.

[FR Doc. 97-21728 Filed 8-14-97; 8:45 am]

BILLING CODE 3710-92-P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Proposed collection; comment request.

SUMMARY: The Director, Information Resources Management 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 October 14, 1997.

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, Information Resources Management 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: August 11, 1997.

Gloria Parker,

Director, Information Resources Management Group.

Office of Educational Research and Improvement

Type of Review: Extension.

Title: Common Core of Data (CCD) Surveys.

Frequency: Annually.

Affected Public: State, local or Tribal Gov't, SEAs or LEAs.

Reporting Burden and Recordkeeping: Responses: 57.

Burden Hours: 9,635.

Abstract: The CCD Survey collects data annually from state education agencies about student enrollments, graduation, dropout; education staff; school and agency characteristics; and revenues and expenditures for public elementary and secondary education. The Department will use this information to provide an official listing of public elementary and secondary schools and education agencies in the United States; and provide basic information and descriptive statistics on public elementary and secondary schools and schooling, including school finance.

Office of Postsecondary Education

Title: Federal Direct Stafford/Ford Loan and Federal Direct Unsubsidized Stafford/Ford Loan Promissory Note and Disclosure.

Frequency: On occasion.

Affected Public: Individuals or households.

Annual Reporting and Recordkeeping Hour Burden:

Responses: 2,600,000.

Burden Hours: 433,160.

Abstract: This form is the means by which a Federal Direct Stafford/Ford and/or Federal Direct Unsubsidized Stafford/Ford Loan borrower promises to repay his or her loan.

Office of Postsecondary Education

Title: Federal Direct PLUS Loan Application and Promissory Note.

Frequency: On occasion.

Affected Public: Individuals or households.

Annual Reporting and Recordkeeping Hour Burden:

Responses: 210,000.

Burden Hours: 105,000.

Abstract: This form is the means by which a Federal Direct PLUS Loan borrower promises to repay his or her loan.

Office of Postsecondary Education

Title: Addendum to Federal Direct PLUS Loan Promissory Note Endorser.

Frequency: On occasion.

Affected Public: Individuals or households.

Annual Reporting and Recordkeeping Hour Burden:

Responses: 52,500.

Burden Hours: 26,250.

Abstract: This form is the means by which an endorser for a Federal Direct PLUS Loan borrower with an adverse credit history applies for and promises to repay the Federal Direct PLUS loan if the borrower does not pay it.

[FR Doc. 97-21597 Filed 8-14-97; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF ENERGY

Federal Energy Technology Center; Notice of Intent to Issue a Program Research and Development Announcement (PRDA)

AGENCY: Department of Energy (DOE), Federal Energy Technology Center (FETC).

ACTION: Notice.

SUMMARY: Notice is hereby given of the intent to issue a PRDA No. DE-RA26-98FT35008 entitled "Global Climate Change—Novel Concepts for Management of Greenhouse Gases." The PRDA will solicit the submission of innovative, "pathbreaking" concepts to sequester and recycle greenhouse gases, and bring those concepts to a stage of technical development sufficient to prove validity on an engineering scale. Specifically, the objective of the procurement is the development of novel, less costly concepts to sequester and recycle greenhouse gases which include ways to reuse, or store greenhouse gases or their conversion products.

DATES: Requests for information concerning the solicitation should be submitted in writing at the address in the **FOR FURTHER INFORMATION CONTACT** section, by facsimile at 304/285-4683, or by E-mail to raymond.jarr@fetc.doe.gov. Telephone requests for the solicitation package will not be accepted.

ADDRESSES: Acquisition and Assistance Division, U.S. Department of Energy, Federal Energy Technology Center, P.O. Box 880, Morgantown, WV 26507-0880.

FOR FURTHER INFORMATION CONTACT: Raymond R. Jarr, Contracting Officer, U.S. Department of Energy, Federal Energy Technology Center, P.O. Box 880, Morgantown, WV 26507-0880; Telephone (304) 285-4088.

SUPPLEMENTARY INFORMATION: The concepts can include chemical or biological conversion methods, as well as, physical storage. The greenhouse gases of interest are CO₂, CH₄, and N₂O associated with the production and use of fossil fuels. Science-based, less costly concepts are sought which are broadly applicable and potentially able to reduce emissions well below those resulting from increased efficiency of fossil-fuel use. In addition, fundamental work prior to development of pathbreaking technologies is acceptable. Sequestration is a very broad term which encompasses a variety of ways to recycle or store the gas, or the carbon from the gases, in a form that will remain stable for centuries. Recycling refers to the ability to reuse carbon contained in fossil fuels or in the

atmosphere and thus, avoid the further combustion of fossil fuels.

Awards resulting from the solicitation will be divided into three Phases. Phase I involves a technical and preliminary economic assessment of proposed concept; Phase II involves laboratory- and bench-scale development of the proposed technology; and Phase III involves pilot or larger scale testing to bring the technology to an engineering scale. An industrial company will be required to perform at least 30 percent of the effort in Phase III. Offerors are encouraged to seek additional sources of funding for any or all phases. Multiple awards are expected for Phase I with a competitive down selection process occurring at the completion of Phases I and II.

The solicitation will be available upon written request to FETC or on the Internet at <http://www.fetc.doe.gov/business/solicita.html>. Those prospective offerors who obtain a copy of the solicitation through the Internet should check the location frequently for any solicitation amendments. Those prospective offerors who request in writing a copy of the solicitation will receive an electronic version of the solicitation on diskette in a WordPerfect 6.1 format. Solicitations will not be distributed in paper form. Requests for information concerning the solicitation should be submitted in writing at the address in the **FOR FURTHER INFORMATION CONTACT** section, by facsimile at 304/285-4683, or by E-mail to raymond.jarr@fetc.doe.gov. All requests should reference the PRDA solicitation number and title, and should include a point-of-contact at the requestor's location. Telephone requests for the solicitation package will not be accepted. The solicitation will be available on or about September 1, 1997. The exact date and time for the submission of proposals will be indicated in the solicitation. However, at least a sixty day response time is currently planned. It is DOE's desire to encourage the widest participation including the involvement of small business concerns, and small disadvantaged business concerns. As a consequence, Phase I of this procurement is a partial set-aside. Subsequent down selections at the end of Phases I and II will not include partial set-aside preferences. In accordance with FAR 52.232-18, "Availability of Funds," funds are not presently available for this procurement. The Government's obligation under this contract is contingent upon the

availability of appropriated funds from which payment for contract purposes can be made.

Dated: August 8, 1997.

Randolph L. Kesling,

Supervisory Contract Specialist, Acquisition and Assistance Division.

[FR Doc. 97-21659 Filed 8-14-97; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IN97-3-000]

Arkansas Oklahoma Gas Corporation; Order Instituting Proceeding

Issued August 8, 1997.

Before Commissioners: James J. Hoecker, Chairman; Vicky A. Bailey, William L. Massey, and Donald F. Santa, Jr.

Arkansas Oklahoma Gas Corporation (AOG) is a local natural gas distribution company in the Fort Smith, Arkansas area. It provides interruptible transportation (IT) of natural gas in interstate commerce subject to a blanket certificate issued under section 284.224 of the Commission's regulations.¹ In a complaint to the Enforcement Task Force, a potential shipper stated that AOG's IT service agreements contain a "sales provision" requiring the shipper to sell gas to AOG when AOG determines that the gas is needed to protect AOG's sales to its local customers. The sales provision in AOG's IT agreements may violate sections 4 (a) and 4(b) of the Natural Gas Act (NGA),² section 311 (a)(2) of the Natural Gas Policy Act of 1978 (NGPA),³ and sections 284.9(b)(1), 284.123(a) and 284.123(e) of the Commission's regulations relating to transportation under the blanket certificate.⁴

This order establishes a proceeding pursuant to NGA sections 4, 5 and 16 and NGPA sections 211 and 501.⁵ We are requiring AOG to show why it has not violated NGA sections 4(a) and 4(b), NGPA section 311(a)(2), or sections 284.9(b)(1), 284.123(a) and 284.123(e) of the Commission's regulations. We are also directing AOG to respond to data and document requests that relate to AOG's blanket certificate transportation.

I. Background

AOG makes direct sales to 60,000 residential and industrial customers in four Oklahoma and five Arkansas counties surrounding Fort Smith.⁶ AOG obtains system supply from more than 450 local production input points scattered throughout its system.⁷

AOG received its Order No. 63⁸ blanket certificate from the Commission on November 13, 1985.⁹ In particular, this certificate permits AOG to transport gas in interstate commerce under the same conditions as apply to transportation by intrastate pipelines under section 311(a)(2) of the Natural Gas Policy Act of 1978 (NGPA).¹⁰ These conditions are set forth in Part 284, Subpart C of the Commission's regulations. Section 284.224(e)(1) of the regulations provides that, as relevant here, any transportation transaction under an Order No. 63 blanket certificate is subject to the Subpart C terms and conditions and reporting requirements.¹¹ In 1994, AOG transported 8,334,725 MMBtu pursuant to its Order No. 63 authority, as compared to 13,698,875 MMBtu that AOG distributed to retail customers.¹²

In discussions with the Task Force, AOG stated that its IT agreements under its blanket certificate contain the following "sales provision" or a similar provision:

Shipper agrees to sell to Transporter gas from the wells listed in the Exhibit "A", on a best efforts basis, when, in Transporter's judgment, the purchase of such gas is necessary to protect the continuity of gas service to Transporter's gas purchasing customers. Such a right to purchase from

Shipper shall be up to the volumes sufficient for Transporter to cease curtailment. Any volumes in excess of those required to enable Transporter to meet its customers [sic] needs which Shipper can deliver to Transporter and which Transporter can transport will thereupon be transported pursuant to other provisions of the gas transportation agreement. Transporter will first balance gas deliveries and redeliveries and if Transporter is unable to balance them it will purchase the gas at the greater of the W.A.COG [sic] as filed with the Arkansas Public Service Commission for AOG system purchases or the "net back" price plus Transporter's transportation attributable to Purchaser's contract. (Use average W.A.COG for preceding twelve months.) Transporter further has the right to purchase transportation gas not currently flowing. These pricing provisions can be changed by mutual consent between the parties. This pricing provision is also subject to other pricing provisions set forth in any gas purchase contracts between Shipper and Transporter. Transporter's right to purchase gas hereunder shall be in effect as to any well listed in Exhibit "A" so long as this agreement is in effect.

Pursuant to 18 C.F.R. § 284.123(e), AOG was required to file an operating statement concerning its transportation under the blanket certificate.¹³ The statement must "describe [] how the pipeline will engage in these transportation arrangements, including operating conditions, such as, quality standards and financial viability of the shipper."¹⁴ On March 22, 1988, AOG filed an amended operating statement with the Commission that does not refer to the sales provision.

On June 23, 1997, AOG submitted a "Statement of Position and Offer of Settlement" (statement), pursuant to Rules 1b.18 and 1b.19 of the Commission's Rules Relating to Investigations.¹⁵ AOG requests confidential treatment for the statement. The statement (apart from the offer of settlement) is a legal argument that does not contain proprietary or otherwise privileged information that would be protected from disclosure under the Freedom of Information Act. AOG has not provided any reason why its legal analysis should not be made public. Therefore, the Commission grants AOG's request for confidential treatment for the offer of settlement and otherwise denies its request for confidential treatment of the remainder of the statement. The Commission addresses

⁶ See AOG's March 22, 1995 filing in Docket No. PR95-4-000, AOG's most recent rate case before the Commission.

⁷ *Id.*

⁸ FERC Stats. & Regs. (Regulations Preambles 1977-1981) ¶ 30,118 (1980).

⁹ Arkansas Oklahoma Gas Corporation, 33 FERC ¶ 61,197 (1995).

¹⁰ 15 U.S.C. § 3371(a)(2) (1994).

¹¹ When AOG received its Order No. 63 blanket certificate, the Commission regulated AOG as a "natural gas company" pursuant to the NGA. As such, AOG had received certificates under NGA section 7 for constructing and operating facilities within this Commission's jurisdiction. In 1989, the Commission held that the Uniform Regulatory Jurisdiction Act of 1988 transferred exclusive jurisdiction over AOG's transportation of gas to ultimate consumers from the Commission to the Arkansas Public Service Commission and the Oklahoma Corporation Commission. Arkansas Oklahoma Gas Corporation, 48 FERC ¶ 61,338 (1989). As a result, except for the blanket certificate, the Commission vacated all NGA section 7 certificates it had previously issued to AOG, effective October 6, 1988. Nonetheless, AOG remains subject to the Commission's jurisdiction to the extent necessary to enforce the terms and conditions of the blanket certificate. *Id.*

¹² AOG's May 9, 1995 filing in Docket No. PR95-4-000, Answer to Item (2), p. 2 of 2.

¹³ This requirement applies to AOG's transportation by virtue of section 284.224(e)(1) of the Commission's regulations.

¹⁴ 18 C.F.R. § 284.123(e).

¹⁵ 18 C.F.R. § 1b.18, 19 (1996). These rules permit a person to submit a memorandum setting forth its position on matters relevant to an investigation.

¹ 18 C.F.R. § 284.224 (1996).

² 15 U.S.C. 717c (a), (b) (1994).

³ 15 U.S.C.A. § 3371(a)(2) (1994).

⁴ 18 C.F.R. §§ 284.9(b), 284.123(a), 284.123(e) (1996).

⁵ 15 U.S.C. 717c, 717d, 717o, 3371, 3411 (1994).

below the substantive arguments contained in the statement.

II. Discussion

With respect to its transportation under its blanket certificate, AOG is subject to section 4 of the NGA. NGA section 4(a) requires that all rules and regulations affecting or pertaining to rates or charges for AOG's blanket certificate transportation be just and reasonable. The transportation service for which shippers pay AOG's rates includes a requirement that shippers sell gas to AOG, at AOG's discretion, to help it meet its own system supply requirements. AOG's sales provision appears to be an unreasonable rule or regulation relating to its rates for interstate IT service. Moreover, in determining its rates for transportation service, AOG does not appear to have addressed the value of the "back-up" supply service it requires of shippers. Therefore, to the extent AOG has required interstate shippers to agree to the sales provision, AOG appears to have imposed an unreasonable regulation relating to its rates for blanket certificate transportation, in violation of NGA section 4(a).

NGA section 4(b) prohibits AOG from any undue preference or discrimination with respect to its transportation under the Order No. 63 blanket certificate. The Commission has implemented this prohibition by subjecting AOG's blanket certificate transportation to section 284.9(b)(1) of the Commission's regulations. Under this provision, AOG must provide interruptible service "without undue discrimination, or preference, including undue discrimination or preference in the quality of service provided, the duration of service, the categories, prices, or volume of natural gas to be transported, customer classification, or undue discrimination or preference of any kind." With respect to its interruptible transportation, AOG is "held essentially to the same non-discriminatory access standards as an interstate pipeline providing NGA section 7 service."¹⁶

By tying its interstate transportation to the sales provision, AOG appears to have unduly discriminated against current and potential shippers, in violation of NGA section 4(b) and section 284.9(b)(1) of the Commission's regulations.¹⁷ In addition, AOG appears

to have violated section 4(b) and section 284.9(b)(1) by failing to disclose the sales provision in the operating statement AOG filed with the Commission.¹⁸

AOG's blanket certificate subjects AOG's interstate IT service to the terms and conditions under which intrastate pipelines provide transportation pursuant to NGA section 311(a)(2). This transportation, which must be subject to fair and equitable rates and charges pursuant to section 284.123(a) of the Commission's regulations, carries the same nondiscriminatory conditions as transportation by interstate pipelines.¹⁹ AOG's tying of its transportation to the sales provision appears to be an unjust and inequitable condition on its interstate transportation service, in violation of NGA section 311(a)(2) and section 284.123(a) of the Commission's regulations.

Further, AOG's failure to include the sales provision in its operating statement appears to have violated section 284.123(e), which requires the statement to be filed. A requirement that a shipper agree to sell gas to AOG appears to be sufficiently central to "how the pipeline will engage in [Order No. 63] transportation arrangements" that AOG must disclose it in its operating statement.

In its statement, AOG asserts that the Commission does not have any authority over the sales provision. AOG argues that because the sales provision relates to AOG's gas purchases for the purpose of selling gas to its distribution customers, the provision is exempted from Commission jurisdiction pursuant to NGA section 1(b).

Contrary to AOG's argument, the Commission has jurisdiction over the sales provision because AOG conditions Order No. 63 transportation on this provision. AOG's blanket certificate

transportation service offered under this rule would constitute undue discrimination in violation of the non-discriminatory access condition * * * if the costs of such services are not properly allocable to a fully-allocated transportation rate.")

¹⁸ Id. at 31,505 ("[R]easonable operating conditions imposed routinely by pipelines or shippers do not *per se* violate the non-discriminatory access provision, provided that such conditions are stated 'up-front' in the pipeline's transportation tariffs on file with the Commission and are applied by the pipeline fairly to all similarly-situated shippers and shipments." [emphasis in original]). In lieu of tariffs, holders of Order No. 63 blanket certificates file operating statements setting forth the conditions under which they will provide interstate transportation. Order No. 436-A, FERC Stats. & Regs. ¶ 30,675 at 31,692-93. Thus, even if AOG's sales provision were reasonable, it appears that AOG is violating section 284.9(b)(1) because its operating statement does not disclose the provision.

¹⁹ *Southwestern*, *supra* n. 16 and *Transok, Inc.*, 54 FERC ¶ 61,229 at 61,673 (1991).

permits the company to conduct transportation permitted by NGA section 311.²⁰ Under NGA section 311(c), the Commission may prescribe terms and conditions for such transportation.²¹ The legislative history indicates that section 311 "provides authority for the Commission to condition approval of the sale, transportation, or exchange under this section upon such specified terms and conditions as it deems appropriate."²² The Commission has recognized its authority to condition section 311 transportation in numerous decisions.²³ Thus, the Commission has authority to determine whether the sales provision is an appropriate condition of AOG's transportation, and to require AOG to delete the condition upon a finding that it is not appropriate.

AOG also argues that the sales provision is "directly tied to its LDC state-regulated service obligation." Statement at 9. The Commission would have jurisdiction over the sales provision as an encumbrance on transportation in interstate commerce, even if the state commission had expressly authorized it, because Order No. 63 preempts state law.²⁴ In addition, contrary to AOG's assertion, the portion of AOG's Arkansas Public Service Commission tariff that the company provided at Exhibit B to its statement makes no mention of the sales provision. In any event, if AOG believes that the sales provision contributes to its ability to perform its state authorized service obligations, it can remove the provision from its interruptible transportation contracts and execute separate, voluntary sales agreements that are not a prerequisite for receiving Order No. 63 service.

²⁰ Order No. 63, FERC Stats. & Regs. ¶ 30,118, at 30,825 (1980). The Commission established these conditions pursuant to NGA section 7(e), 15 U.S.C. § 717f(e), which granted the Commission authority to attach to the certificate "such reasonable terms and conditions as the public convenience and necessity may require."

²¹ See, e.g., *Associated Gas Distributors v. FERC*, 824 F.2d 981, 1016 (D.C. Cir. 1987) ("the authority of § 311(c) * * * allows [the Commission] to prescribe 'terms and conditions'" for section 311 transportation).

²² Conference Committee Report; Joint Explanatory Statement, H. Rept. 95-1752, at 106-109 (1978); S. Rept. 95-1126, at 106-109 (1978), reprinted at 5 *Natural Gas Policy Act Information Service* ¶ 311:210 at p. 4.

²³ E.g., *Missouri Gas Energy v. Williams Natural Gas Company*, 79 FERC ¶ 61,204 (1997) (section 311 construction projects must comply with the environmental requirements of section 157.206(d) of the Commission's regulations); *Pacific Gas and Electric Company*, 69 FERC ¶ 61,140 at 61,505 (1994) (acceptance of an Order No. 63 blanket certificate authorizes the Commission to enforce terms and conditions of the certificate).

²⁴ See, e.g., Order No. 63, at 30,827.

¹⁶ *Southwestern Public Service Co. v. Red River Pipeline*, 74 FERC ¶ 61,133 at 61,473 (1996) (*Southwestern*).

¹⁷ See Order No. 436, FERC Stats. & Regs. [Regs. Preambles 1982-1985] ¶ 30,655 at 31,511 (1985) ("arrangements by pipelines that tie or 'bundle' gathering, production, storage or other services not requested by shippers to self-implementing

AOG also contends that its interruptible transportation service is a gathering service that has been regulated by the Commission as a matter of convenience. Statement at 15. This argument proves too much, for if AOG's facilities are exempt gathering facilities, it should not have a blanket certificate. Indeed, AOG specifies that it does not want the Commission to declare that AOG's facilities are "gathering." Statement at 17 n.25.

AOG next argues that the Commission cannot require it to amend its operating statement by including the sales provision, and adds that it is not aware that the Commission has ever required an intrastate pipeline or an Order No. 63 transporter to amend its operating statement. Statement at 18–19. AOG quotes from *Transok, Inc.*²⁵ for the proposition that, while the Commission can reject or suspend proposed changes in tariff provisions that interstate pipelines file under NGA section 4, it cannot reject or suspend an Order No. 63 transporter's operating statement filed under NGPA section 311. Here, the Commission is not considering whether to reject or suspend AOG's operating statement. Instead, the Commission is exercising its authority to determine whether AOG's sales provision is lawful and whether it should be included in AOG's operating statement. That is consistent with our actions in *Transok*. There, the Commission determined, *inter alia*, that an intrastate pipeline that provides section 311 service must curtail firm shippers on a nondiscriminatory basis. In that proceeding, the Commission directed Transok to amend its operating statement to meet this requirement.²⁶

AOG next cites *CNG Transmission Corporation*²⁷ for the proposition that the Commission can only recommend (not require) the terms and conditions under which an LDC transacts business on its system. In that order, the Commission declined to specify how an LDC should broker transportation capacity to end users receiving the LDC's non-jurisdictional distribution service. Here, the Commission is exercising its authority over the terms of AOG's jurisdictional transportation.

Finally, AOG suggests that because the Commission approved its rates three times since it filed its operating statement, the sales provision is insulated from further review.

Statement at 19. But the Commission never addressed the sales provision when it approved AOG's rates, and there is no indication that the Commission was aware of it.

The Commission will require AOG to show why, by including the sales provision in its interstate IT agreements, and by not disclosing this provision in its operating statement, it has not violated and is not violating NGA sections 4(a) and 4(b), NGPA section 311(a)(2) and sections 284.9(b)(1), 284.123(a) and 284.123(e) of the Commission's regulations.

The Commission orders:

(A) Within 30 days of the issuance of this order, AOG shall:

(1) File an answer to the allegations of violations that conforms to the requirements of Rule 213 of the Commission's Rules, 18 C.F.R. § 385.213 (1996). In its answer, AOG shall admit or deny, specifically and in detail, each allegation set forth in Part II of this order, and shall set forth every defense relied on. If an allegation is only partially accurate, AOG shall specify that part of the allegation it admits and that part of the allegation it denies.

(2) Show why, by including the sales provision in its interstate IT agreements, it has not violated and is not violating NGA sections 4(a) and 4(b), NGPA section 311(a)(2) and section 284.9(b)(1) of the Commission's regulations.

(3) Show why, by not disclosing the sales provision in its operating statement, it has not violated and is not violating sections 284.9(b)(1) and 284.123(e) of the Commission's regulations.

(4) AOG shall separately state the facts and the arguments that it advances. AOG must support with exhibits, affidavits and/or prepared testimony any facts that it alleges. AOG's statement of material facts must include citation to supporting data. In addition to its answer, AOG must respond to the following requests for information and documents. All materials must be subscribed and verified as set forth in sections 385.2005 (a) and (b)(2) of the Commission's regulations, 18 C.F.R. §§ 385.2005 (a) and (b)(2) (1996).

(a) State the full legal name and business address of each entity with which AOG has executed a currently effective Order No. 63 transportation agreement. For each entity identified, provide a copy of the transportation agreement, as amended. For each transportation agreement provided, state the expiration date of the agreement if it is not clearly set forth in the copy of the agreement.

(b) State whether AOG has ever invoked the sales provision (or a similar

provision) for any transportation agreement provided in response to (a).

(c) For each transportation agreement for which AOG has invoked the sales provision (or a similar provision), provide the following information and documents:

(i) The date on which AOG invoked the provision;

(ii) The period during which the shipper sold gas to AOG pursuant to the provision;

(iii) The quantity and sales price of the gas the shipper sold to AOG, and the amount of the transportation charges AOG refunded to the shipper; and

(iv) All documents relating to AOG's purchase of gas under the provision or notification to the shipper that sales would no longer be required under the provision.

(B) AOG's request for confidential treatment for its June 23, 1997 statement is granted with respect to the offer of settlement contained therein and denied with respect to the remainder of the statement.

(C) Notice of this proceeding will be published in the **Federal Register**. Interested parties will have 20 days from the date of publication of the notice to intervene.

By the Commission.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 97–21613 Filed 8–14–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP97–663–000]

CNG Transmission Corporation; Notice of Request Under Blanket Authority

August 11, 1997.

Take notice that on July 23, 1997, CNG Transmission Corporation (CNG), 445 West Main Street, Clarksburg, West Virginia 26301, filed in Docket No. CP97–663–000 a request pursuant to Sections 157.205, 157.211 and 157.216 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.211 and 157.216) for authorization to expand the facilities at the existing Jefferson Measuring and Regulation Station (Jefferson Station) near Jefferson, Frederick County, Maryland, under CNG's blanket certificate issued in Docket No. CP82–537–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

²⁵ 54 FERC ¶61,229 at 61,672 n.5 (1991).

²⁶ *Id.* at 61,676. In response, Transok filed an amended operating statement that deleted a provision that the Commission determined might discriminate against interstate shippers. 56 FERC ¶61,275 at 62,083 n.12 (1991).

²⁷ 55 FERC ¶61,189 at 61,627 (1991).

CNG states that the existing Jefferson Station must be expanded to provide additional natural gas service to Washington Gas Light Company (Washington Gas Light). CNG states that Washington Gas Light has requested an increase from 2,000 Dth/day to 24,000 Dth/day in the natural gas service CNG provides them through the Jefferson Station. CNG states that the maximum daily design delivery capacity of the modified Jefferson Station equipment is 24,000 Dth/day.

CNG states that under Letter Agreement dated May 29, 1997, Washington Gas Light has consented to execute a new service agreement with CNG for additional deliveries of gas. CNG also states that the total estimated cost of the construction is \$1,200,000, and that Washington Gas Light will reimburse CNG for one half of the costs of such expansion upon completion of the station.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 97-21610 Filed 8-14-97; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP97-681-000]

Florida Gas Transmission Company; Notice of Request Under Blanket Authorization

August 11, 1997.

Take notice that on August 4, 1997, Florida Gas Transmission Company (FGT), 1400 Smith Street, Houston, Florida 77002, filed in Docket No. CP97-681-000 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 construct and operate a delivery point in Levy County, Florida under FGT's blanket certificate issued in Docket No. CP82-553-000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

FGT proposes to construct, operate, and own an additional delivery point for West Florida Natural Gas Company (West Florida) at or near mile post 53.2 on its existing Inglis Lateral in Levy County, Florida. FGT states that the subject delivery point will include a tap, a valve, minor connecting pipe, electronic flow measurement equipment, and other related appurtenant facilities necessary for FGT to deliver up to a maximum of 200 MMBtu per day and 73,000 per year. FGT will be reimbursed for the construction costs which is estimated at \$57,000. FGT further states that West Florida will construct, own, and operate the meter and regulation station.

FGT states that the delivery point is not prohibited by its existing tariff and that it has sufficient capacity to accomplish deliveries without detriment or disadvantage to other customers. The proposed delivery point will not have an effect on FGT's peak day and annual deliveries and the total volumes delivered will not exceed total volumes authorized prior to this request.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 97-21611 Filed 8-14-97; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 1218]

Georgia Power Company; Notice of Availability of Study Results and Request for Additional Studies

August 11, 1997.

Georgia Power Company is currently engaged in the process of obtaining from the Federal Energy Regulatory Commission (Commission) a new license for the Flint River Hydroelectric Project (FERC No. 1218). The current license for the project is due to expire on September 30, 2001. The project is located on the Flint River, near the City of Albany, in Dougherty and Lee Counties, Georgia. Under the Commission's Regulations, an application for license for the project must be filed by September 30, 1999. Georgia Power Company is managing relicensing activities in cooperation with a team of federal and state resource agencies, conservation groups, and local governments (the Consultation Team).

Pursuant to the Energy Policy Act of 1992, and the Commission's Regulations, Georgia Power Company intends to prepare a Draft Environmental Assessment (DEA) as part of the license application, to be filed with the Commission, for the project. A public scoping meeting was held on September 12, 1995 to identify the scope of environmental issues that should be analyzed in the DEA.

Based on information contained in Scoping Document I, and following receipt of additional informational from resource agencies and other interested parties, Georgia Power Company prepared and circulated Scoping Document II. Study plans, designed to address the environmental concerns raised during the scoping process, were subsequently prepared by Georgia Power Company and their environmental consultant. The study plans were then finalized, and studies were undertaken from late Spring 1996 through late Spring 1997. During the field studies, Georgia Power Company and their environmental consultant worked closely with the participating agencies to coordinate and refine the studies. During the period from August 15, 1997 until October 14, 1997, these study reports will be available for public review in Georgia Power Company's public library at its offices at 333 Piedmont Avenue in Atlanta, Georgia. The study reports will also be available in the Commission's Public Reference Room at 888 1st Street, NE in

Washington, D.C. The public is invited to review these documents and to file comments on the adequacy of these studies in addressing issues raised during the scoping process. Comments on these studies and requests for any additional studies are due by October 14, 1997.

Because Section 4.32(b)(7) of the Commission's regulations has been previously waived, we are requesting that if any resource agency, Indian tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the project on its merit, the resource agency, Indian tribe, or person must file a request for a study with the Secretary of the Commission at 888 First Street, NE, Washington, DC 20426 by October 14, 1997, and serve a copy of the request on Mr. Mike Phillips, Georgia Power Company, Bin 20020, 333 Piedmont Avenue, Atlanta, GA 30308.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 97-21614 Filed 8-14-97; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER97-3428-000]

Tri-Valley Corporation; Notice of Issuance of Order

August 11, 1997.

Tri-Valley Corporation (Tri-Valley) submitted for filing a rate schedule under which Tri-Valley will engage in wholesale electric power and energy transactions as a marketer. Tri-Valley also requested waiver of various Commission regulations. In particular, Tri-Valley requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Tri-Valley.

On August 6, 1997, pursuant to delegated authority, the Director, Division of Applications, Office of Electric Power Regulation, granted requests for blanket approval under part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Tri-Valley 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 385.214).

Absent a request for hearing within this period, Tri-Valley is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of Tri-Valley's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is September 5, 1997. Copies of the full text of the order are available from the Commission's Public Reference Branch, 888 First Street, N.E. Washington, D.C. 20426.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 97-21612 Filed 8-14-97; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER97-3361-000, et al.]

Indianapolis Power & Light Company, et al.; Electric Rate and Corporate Regulation Filings

August 8, 1997.

Take notice that the following filings have been made with the Commission:

1. Indianapolis Power & Light Company

[Docket No. ER97-3361-000]

Take notice that on June 18, 1997, Indianapolis Power & Light Company (IPL), tendered for filing a power sales agreement executed between IPL and Commonwealth Edison Company.

Copies of this filing were sent to the Indiana Utility Regulatory Commission and Commonwealth Edison Company.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

2. Louisiana Public Service Company v. Entergy Services, Inc.

[Docket No. EL97-50-000]

Take notice that on February 5, 1997, the Louisiana Public Service Commission filed a second amended

complaint under Sections 205 and 206 of the Federal Power Act, 16 U.S.C. §§ 824d and 824e against Entergy Services, Inc. As the representative of Entergy Corporation and its operating companies. The complaint seeks a revision of the Entergy System Agreement based upon allegations that the terms of the agreement, under current circumstances, are unjust and unreasonable. Specifically, the complaint alleges that the absence of any provision in the System Agreement excluding curtailable load from the determination of a company's load responsibility under the System Agreement results in an unjust and unreasonable cost allocating to companies that do not cause these costs to be incurred, and results in cross-subsidization among the companies. Additionally, it is alleged that the absence of any provision in MSS-3 for allocating marginal energy costs to customers that purchase energy under Entergy's "real time pricing" rate schedules at the retail level discriminates against a company that offers real time pricing.

Comment date: September 8, 1997, in accordance with Standard Paragraph E at the end of this notice.

3. Zond Development Corporation; Zond Minnesota Development Corporation II

[Docket Nos. ER97-2532-001; ER97-2904-001]

Take notice that on August 1, 1997, Zond Development Corporation and Zond Minnesota Development Corporation II tendered for filing in compliance with the Commission's July 17, 1997 order in the above-referenced dockets, a compliance filing informing the Commission that they are currently bound by a code of conduct governing their relationship with Portland General Electric Company. That code of conduct, which is attached to the filing for informational purposes, was initially filed with the Commission by Enron Power Marketing, Inc., on September 20, 1996, in Docket No. ER96-3065-000, and was accepted by the Commission in *Enron Corp.*, 78 FERC ¶ 61,179 (1997).

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

4. San Diego Gas & Electric Company

[Docket No. ER97-3638-000]

Take notice that on July 28, 1997, San Diego Gas & Electric Company tendered for filing an amendment in the above-docketed proceeding.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

5. San Diego Gas & Electric Company

[Docket No. ER97-3803-000]

Take notice that on July 21, 1997, San Diego Gas & Electric Company (SDG&E), tendered for filing Notices of Cancellation for the following:

1. Rate Schedule FERC No. 38—Interconnection Agreement between San Diego Gas & Electric Company and Tucson Electric Power Company, dated July 27, 1979, to be terminated September 15, 1997;

2. Rate Schedule FERC No. 48—Interconnection Agreement between San Diego Gas & Electric Company and Plains Electric Generation and Transmission Cooperative, Inc., dated August 4, 1982, to be terminated September 15, 1997;

3. Rate Schedule FERC No. 70—Power Coordination Agreement between San Diego Gas & Electric Company and Arizona Public Service Company, dated December 23, 1985, to be terminated September 15, 1997;

4. Rate Schedule FERC No. 68—Interconnection Agreement between San Diego Gas & Electric Company and Public Service Company of New Mexico, dated September 9, 1985, to be terminated September 15, 1997;

5. Service Agreement Utah—1C of FERC Electric Tariff Volume No. 2 between San Diego Gas & Electric Company and Utah Power & Light Company, dated April 1, 1982, to be terminated September 15, 1997;

6. Rate Schedule FERC No. 72—Interchange Agreement between San Diego Gas & Electric Company and Deseret Generation & Transmission Cooperative, dated September 2, 1986, to be terminated September 15, 1997; and

7. Letter Agreement for Emergency Exchange Service between San Diego Gas & Electric Company and Pacific Power & Light Company, dated January 3, 1980, to be terminated September 15, 1997.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

6. Niagara Mohawk Power Corporation

[Docket No. ER97-3804-000]

Take notice that on July 21, 1997, Niagara Mohawk Power Corporation (NMPC), tendered for filing with the Federal Energy Regulatory Commission an executed Transmission Service Agreement between NMPC and New Energy Ventures, Inc. This Transmission Service Agreement specifies that New Energy Ventures, Inc., has signed on to and has agreed to the terms and conditions of NMPC's Open Access Transmission Tariff as filed in Docket No. OA96-194-000. This Tariff, filed

with FERC on July 9, 1996, will allow NMPC and New Energy Ventures, Inc., to enter into separately scheduled transactions under which NMPC will provide transmission service for New Energy Ventures, Inc., as the parties may mutually agree.

NMPC requests an effective date of July 17, 1997. 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 New Energy Ventures, Inc.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

7. Niagara Mohawk Power Corporation

[Docket No. ER97-3805-000]

Take notice that on July 21, 1997, Niagara Mohawk Power Corporation (NMPC), tendered for filing with the Federal Energy Regulatory Commission an executed Transmission Service Agreement between NMPC and NP Energy, Inc. This Transmission Service Agreement specifies that NP Energy, Inc. has signed on to and has agreed to the terms and conditions of NMPC's Open Access Transmission Tariff as filed in Docket No. OA96-194-000. This Tariff, filed with FERC on July 9, 1996, will allow NMPC and NP Energy, Inc. to enter into separately scheduled transactions under which NMPC will provide transmission service for NP Energy, Inc. as the parties may mutually agree.

NMPC requests an effective date of July 15, 1997. 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 NP Energy, Inc.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

8. Atlantic City Electric Company

[Docket No. ER97-3806-000]

Take notice that on July 21, 1997, Atlantic City Electric Company (Atlantic Electric), tendered for a filing service agreement under which Atlantic Electric will sell capacity and energy to Jersey Central Power and Light Company, Metropolitan Edison Company and Pennsylvania Electric Company (collectively, GPU Energy) under Atlantic Electric's market-based rate sales tariff. Atlantic Electric requests the agreement be accepted to become effective on July 21, 1997.

Atlantic Electric states that a copy of the filing has been served on GPU Energy.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

9. Illinois Power Company)

[Docket No. ER97-3807-000]

Take notice that on July 22, 1997, Illinois Power Company (Illinois Power), 500 South 27th Street, Decatur, Illinois 62526, tendered for filing a Power Sales Tariff, Service Agreement under which The Dayton Power & Light Company will take service under Illinois Power Company's Power Sales Tariff. The agreements are based on the Form of Service Agreement in Illinois Power's tariff.

Illinois Power has requested an effective date of July 16, 1997.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

10. Southwestern Public Service Company

[Docket No. ER97-3808-000]

Take notice that on July 22, 1997, Southwestern Public Service Company (Southwestern), submitted an executed service agreement under its open access transmission tariff with Vitol Gas & Electric, LLC. The service agreement is for umbrella non-firm point-to-point transmission service.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

11. Southern Indiana Gas and Electric Company

[Docket No. ER97-3809-000]

Take notice that on July 22, 1997, Southern Indiana Gas and Electric Company (SIGECO), tendered for filing one (1) service agreement for non-firm transmission service under Part II of its Transmission Services Tariff with NP Energy Inc.

Copies of the filing were served upon each of the parties to the service agreements.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

12. Southern Indiana Gas and Electric Company

[Docket No. ER97-3810-000]

Take notice that on July 22, 1997, Southern Indiana Gas and Electric Company (SIGECO), tendered for filing three (3) service agreements for market based rate power sales under its Market Based Rate Tariff with the following entities:

1. Citizens Power Sales.
2. NP Energy Inc.
3. Virginia Electric and Power Company.

Copies of the filing were served upon each of the parties to the service agreements.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

13. Nevada Power Company

[Docket No. ER97-3811-000]

Take notice that on July 21, 1997, Nevada Power Company (Nevada Power), tendered for filing an Amendment to its Agreement for Transmission Service among Nevada Power Company and Overton Power District No. 5 and Lincoln County Power District No. 1 (Agreement) having a proposed effective date of September 25, 1996. The amendment lowers the rate of return component of the transmission service charge from 13.71% to 12.95%.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

14. The Empire District Electric Company

[Docket No. ER97-3812-000]

Take notice that on July 22, 1997, The Empire District Electric Company (EDE), tendered for filing a service agreement between EDE and Constellation Power Source, Inc., providing non-firm point-to-point transmission service pursuant to the Open Access Transmission Tariff (Schedule OATS) of EDE.

EDE states that a copy of this filing has been served by mail upon Constellation Power Source, Inc., 39 W. Lexington St., Suite 1120, Baltimore, MD 21201.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

15. Louisville Gas and Electric

[Docket No. ER97-3813-000]

Take notice that on July 22, 1997, Louisville Gas and Electric Company, tendered for filing copies of a service agreement between Louisville Gas and Electric Company and NESI Power Marketing under Rate GSS.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

16. Central Illinois Public Service Company

[Docket No. ER97-3814-000]

Take notice that on July 22, 1997, Central Illinois Public Service Company (CIPS), tendered for filing a letter agreement amending CIPS' contract with the City of Newton, Illinois (Newton). The letter agreement lowers the demand charge to Newton for the remainder of the contract term.

CIPS requests an effective date of July 1, 1997, and accordingly, requests that the Commission waive its notice requirements. Copies of this filing have been served on Newton and the Illinois Commerce Commission.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

17. Friendly Power Company LLC

[Docket No. ER97-3815-000]

Take notice that on July 22, 1997, Friendly Power Company LLC (Friendly Power), tendered for filing pursuant to Sections 205 and 207 of the Commission's Rules of Practice and Procedure, 18 CFR 385.205, 385.207, its FERC Rate Schedule No. 1, to be effective 60 days from and after July 22, 1997, and a request for waivers of and blanket approvals under various regulations of the Commission and the Federal Power Act.

Friendly Power's FERC Rate Schedule No. 1 provides for the sale of energy and capacity at market-determined prices mutually agreed upon by the purchaser and Friendly Power. Friendly Power intends to engage in wholesale electric power transactions as a marketer. All power sales shall be made at arms-length; power sales will not be made to any entity affiliated with Friendly Power. Neither Friendly Power nor any of its affiliates owns, operates, or controls any electric power transmission or generation facilities.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

18. Commonwealth Edison Company

[Docket No. ER97-3816-000]

Take notice that on July 22, 1997, Commonwealth Edison Company (ComEd), submitted for filing a Short-Term Firm Service Agreement establishing Commonwealth Edison Company, in its wholesale merchant function (ComEd WMD), and a Non-Firm Service Agreement with Market Responsive Energy, Inc. (MREI), under the terms of ComEd's Open Access Transmission Tariff (OATT). ComEd also submitted a revised Index of Customers reflecting the two new additions and name changes for current customers, Eastex Energy, Inc., and Citizen's Lehman Power Sales.

ComEd requests an effective date of June 25, 1997, for the service agreements, and accordingly seeks waiver of the Commission's requirements. Copies of this filing were served upon ComEd WMD, MREI, El Paso Energy Marketing Company, Citizens Power Sales, and the Illinois Commerce Commission.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

19. The Dayton Power and Light Co.

[Docket No. ER97-3817-000]

Take notice that on July 22, 1997, The Dayton Power and Light Company (DP&L), submitted a service agreement establishing Commonwealth Edison Company (ComEd) as a customer under the terms of DP&L's Market-Based Sales Tariff.

DP&L requests an effective date of June 22, 1997, for the service agreement. Accordingly, DP&L requests waiver of the Commission's notice requirements. Copies of the filing were served upon ComEd and the Public Utilities Commission of Ohio.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

20. Central Louisiana Electric Company, Inc.

[Docket No. ER97-3820-000]

Take notice that on July 23, 1997, Central Louisiana Electric Company, Inc., (CLECO), tendered for filing a service agreement under which CLECO will provide non-firm point-to-point transmission service to Constellation Power Source, Inc., under its point-to-point transmission tariff.

CLECO states that a copy of the filing has been served on Constellation Power Source, Inc.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

21. Union Electric Company

[Docket No. ER97-3821-000]

Take notice that on July 23, 1997, Union Electric Company (UE), tendered for filing a Service Agreement for Firm Point-to-Point Transmission Service between Southern Energy Trading and Marketing, Inc. (SETM) and UE. UE asserts that the purpose of the Agreement is to permit UE to provide transmission service to SETM pursuant to UE's Open Access Transmission Tariff filed in Docket No. OA96-50.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

22. Illinois Power Company

[Docket No. ER97-3822-000]

Take notice that on July 23, 1997, Illinois Power Company (Illinois Power), 500 South 27th Street, Decatur, Illinois 62526, tendered for filing a Power Sales Tariff, Service Agreement under which Duke Power Company, a division of Duke Energy Corporation

will take service under Illinois Power Company's Power Sales Tariff. The agreements are based on the Form of Service Agreement in Illinois Power's tariff.

Illinois Power has requested an effective date of June 24, 1997.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

23. Florida Power & Light Company

[Docket No. ER97-3823-000]

Take notice that on July 23, 1997, Florida Power & Light Company filed a Service Agreement with Virginia Electric and Power Company for service pursuant to Tariff No. 1 for Sales of Power and Energy by Florida Power & Light. FPL requests that each Service Agreement be made effective on June 24, 1997.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

24. MidAmerican Energy Company

[Docket No. ER97-3824-000]

Take notice that on July 23, 1997, MidAmerican Energy Company (MidAmerican) filed with the Commission a Notice of Cancellation pursuant to Section 35.15 of the Commission's Regulations. MidAmerican states that the rate schedules to be canceled effective as of 11:59 p.m. on June 30, 1997 are as follows:

1. Full Requirements Power Agreement dated September 9, 1987, between Iowa Public Service Company (a predecessor company of MidAmerican) and City of Sergeant Bluff, Iowa. This Full Requirements Power Agreement has been designated as MidAmerican Rate Schedule Electric Tariff No. 7, Service Agreement No. 9.

MidAmerican requests a waiver of Section 35.15 to the extent that this Notice of Cancellation has not been filed within the time required by such section. MidAmerican states that this Notice of Cancellation was not filed earlier because the termination of the agreement identified in the Notice of Cancellation was subject to the Commission's acceptance for filing of other contracts submitted for filing in Docket No. ER97-2926-000 which acceptances were issued on June 20, 1997, effective on July 1, 1997. The new agreement, which supplants the agreement being canceled, is entitled Wholesale Requirements Power Sales Agreement and has been designated as MidAmerican Rate Schedule Electric Tariff No. 5, Service Agreement No. 14.

MidAmerican has mailed a copy of this filing to City of Sergeant Bluff, IA,

the Iowa Utilities Board, the Illinois Commerce Commission and the South Dakota Public Utilities Commission.

Comment date: May 5, 1997, in accordance with Standard Paragraph E at the end of this notice.

25. MidAmerican Energy Company

[Docket No. ER97-3825-000]

Take notice that on July 23, 1997, MidAmerican Energy Company (MidAmerican), 666 Grand Avenue, Des Moines, Iowa 50303 submitted for filing with the Commission a Service Agreement dated July 1, 1997, with Williams Energy Services Company (WESC) entered into pursuant to MidAmerican's Rate Schedule for Power Sales, FERC Electric Tariff, Original Volume No. 5 (Tariff).

MidAmerican requests an effective date of July 1, 1997, for this Agreement, and accordingly seeks a waiver of the Commission's notice requirement. MidAmerican has served a copy of the filing on WESC, the Iowa Utilities Board, the Illinois Commerce Commission and the South Dakota Public Utilities Commission.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

26. MidAmerican Energy Company

[Docket No. ER97-3826-000]

Take notice that on July 23, 1997, MidAmerican Energy Company (MidAmerican), 666 Grand Avenue, Des Moines, Iowa 50303 submitted for filing with the Commission a Service Agreement dated June 18, 1997, with Central Iowa Power Cooperative (CIPCO) entered into pursuant to MidAmerican's Rate Schedule for Power Sales, FERC Electric Tariff, Original Volume No. 5 (Tariff).

MidAmerican requests an effective date of July 1, 1997, for this Agreement. MidAmerican has served a copy of the filing on CIPCO, the Iowa Utilities Board, the Illinois Commerce Commission and the South Dakota Public Utilities Commission.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

27. Carolina Power & Light Company

[Docket No. ER97-3827-000]

Take notice that on July 23, 1997, Carolina Power & Light Company tendered for filing a letter approving application for membership in the Western Systems Power Pool (WSPP).

Copies of the filing were served upon the North Carolina Utilities Commission, the South Carolina Public Service Commission, and all WSPP members.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

28. New England Power Pool

[Docket No. ER97-3828-000]

Take notice that on July 23, 1997, the New England Power Pool Executive Committee filed a signature page to the NEPOOL Agreement dated September 1, 1971, as amended, signed by Williams Energy Services Company (Williams Energy). The New England Power Pool Agreement, as amended, has been designated NEPOOL FPC No. 2.

The Executive Committee states that acceptance of the signature page would permit Williams Energy to join the over 120 Participants that already participate in the Pool. NEPOOL further states that the filed signature page does not change the NEPOOL Agreement in any manner, other than to make Williams Energy a Participant in the Pool. NEPOOL requests an effective date of the date of filing of Williams Energy's signature page, or as soon as possible thereafter for commencement of participation in the Pool by Williams Energy.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

29. Southern Company Services, Inc.

[Docket No. ER97-3829-000]

Take notice that on July 23, 1997, Southern Company Services, Inc. (SCSI), acting on behalf of Alabama Power Company, Georgia Power Company, Gulf Power Company, Mississippi Power Company and Savannah Electric and Power Company (collectively referred to as Southern Companies) filed two (2) service agreements under Southern Companies' Market-Based Rate Power Sales Tariff (FERC Electric Tariff, Original Volume No. 4) with the following entities: (i) City of Gainesville, Florida and (ii) DuPont Power Marketing, Inc. SCSI states that the service agreements will enable Southern Companies to engage in short-term market-based rate transactions with these entities.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

30. Market Responsive Energy, Inc.

[Docket No. ER97-3830-000]

Take notice that on July 23, 1997, Market Responsive Energy, Inc. (MREI) filed Electric Power Service Agreements between MREI and Federal Energy Sales, Inc., and American Energy Solutions, Inc.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

31. Kentucky Utilities Company

[Docket No. ER97-3831-000]

Take notice that on July 23, 1997, Kentucky Utilities Company (KU), tendered for filing service agreements between KU and Market Responsive Energy, Inc., and with Pennsylvania Power & Light Company under its Transmission Services (TS), Tariff and with Market Responsive Energy, Inc., under its Power Services (PS) Tariff.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

32. The Detroit Edison Company

[Docket No. ER97-3832-000]

Take notice that on July 23, 1997, The Detroit Edison Company (Detroit Edison) filed a Power Sales Agreement (Power Sales Agreement) between Detroit Edison and DTE Energy Trading, Inc. (DTE Energy Trading), under which Detroit Edison may engage in sales of capacity and energy and the resale of transmission services to its power marketing affiliate, DTE Energy Trading. Detroit Edison requests the Commission to accept the Power Sales Agreement effective as of October 1, 1997.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

33. Cleveland Electric Illuminating Company and The Toledo Edison Company

[Docket No. ER97-3833-000]

Take notice that on July 23, 1997, the Centerior Service Company as Agent for The Cleveland Electric Illuminating Company and The Toledo Edison Company filed Service Agreements to provide Non-Firm Point-to-Point Transmission Service for the following Transmission Customers: Detroit Edison Company, Enron Power Marketing, Rainbow Energy Corporation, and Southern Energy T&M, Incorporated. Services are being provided under the Centerior Open Access Transmission Tariff submitted for filing by the Federal Energy Regulatory Commission in Docket No. OA96-204-000. The proposed effective dates under the Service Agreements are June 26, June 24, June 26, and June 25, of 1997, respectively.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

34. DTE-CoEnergy L.L.C.

[Docket No. ER97-3835-000]

Take notice that on July 23, 1997, DTE-CoEnergy L.L.C. (DTE-CoEnergy) submitted for filing its FERC Electric Rate Schedule No. 1, providing for DTE-

CoEnergy to sell electric capacity and energy at market-based rates. DTE-CoEnergy seeks an effective date of October 1, 1997. DTE-CoEnergy also seeks waiver of certain regulations of the Federal Energy Regulatory Commission consistent with the Commission's treatment of power marketers. DTE-CoEnergy is an indirect affiliate of The Detroit Edison Company and Michigan Consolidated Gas Company. DTE-CoEnergy has included in its filing protections applicable to affiliated power marketers.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

35. Pacific Gas and Electric Company

[Docket No. ER97-3836-000]

Take notice that on July 23, 1997, Pacific Gas and Electric Company (PG&E), tendered for filing revisions to the following agreements between PG&E and the City of Santa Clara, California (City or Santa Clara): 1) the Grizzly Development and Mokelumne Settlement Agreement (Grizzly Agreement), initially filed and accepted in FERC Project No. 137-002; 2) the System Bulk Power Sale and Purchase Agreement (Bulk Power Agreement), initially filed in FERC Docket No. ER87-498-000 and designated as PG&E Rate Schedule FERC No. 108; and 3) the Interconnection Agreement between Pacific Gas and Electric Company and the City of Santa Clara (IA), initially filed in FERC Docket No. ER84-6-000 and designated as PG&E Rate Schedule FERC No. 85.

PG&E's filing as to the Grizzly Agreement and the Bulk Power Agreement proposes rate changes other than rate increases.

PG&E's filing as to the IA proposes revisions to Exhibit A-4 to Appendix A, regarding Firm Transmission Service between Points of Receipt and Points of Delivery.

Copies of this filing were served upon Santa Clara and the California Public Utilities Commission.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

36. John M. Deutch

[Docket No. ID-2430-002]

Take notice that on July 24, 1997, John M. Deutch (Applicant) tendered for filing an application under Section 305(b) to hold the following positions: Director, Consumers Energy Company Director, Schlumberger Limited

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

37. DTE Energy Trading, Inc.

[Docket No. ER97-3834-000]

Take notice that on July 23, 1997, DTE Energy Trading, Inc. (DTE Energy Trading) submitted for filing its FERC Electric Rate Schedule No. 1, providing for DTE Energy Trading to sell electric capacity and energy at market-based rates. DTE Energy Trading seeks an effective date of October 1, 1997. DTE Energy Trading also seeks waiver of certain regulations of the Federal Energy Regulatory Commission consistent with the Commission's treatment of power marketers. DTE Energy Trading is an indirect affiliate of The Detroit Edison Company (Detroit Edison). DTE Energy Trading has included in its filing protections applicable to affiliated power marketers as well as protections to enable DTE Energy Trading to broker Detroit Edison's Power.

Comment date: August 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

38. Central Illinois Public Service Company

[Docket No. OA97-680-000]

Take notice that on July 14, 1997, Central Illinois Public Service Company tendered for filing its Open Access Transmission Service Tariff in compliance with Order No. 888-A.

Comment date: August 22, 1997, 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.

Linwood A. Watson, Jr.,*Acting Secretary.*

[FR Doc. 97-21609 Filed 8-14-97; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Docket No. EC97-48-000, et al.]

Lake Benton Power Partners, LLC, et al.; Electric Rate and Corporate Regulation Filings

August 11, 1997.

Take notice that the following filings have been made with the Commission:

1. Lake Benton Power Partners, LLC

[Docket No. EC97-48-000]

On August 6, 1997, Lake Benton Power Partners, LLC (Lake Benton LLC), P.O. Box 1910, 13000 Jameson Road, Tehachapi, California 93561 submitted for filing an application for approval under Section 203 of the Federal Power Act of the acquisition of a membership interest in Lake Benton LLC by ESI Lake Benton LLC (ESI Lake Benton). No determination has been made that the submittal constitutes a complete filing.

According to the applicant, Lake Benton LLC is developing a wind energy project near Lake Benton, Minnesota that will sell power to Northern States Power Company pursuant to a long-term power purchase agreement. The purchase of a membership interest in Lake Benton LLC by ESI Lake Benton will enable Lake Benton LLC to obtain additional financing necessary to complete the project.

Comment date: August 29, 1997, in accordance with Standard Paragraph E at the end of this notice.

2. Wisconsin Electric Power Company

[Docket No. EL97-47-000]

Take notice that on July 2, 1997, Wisconsin Electric Power Company tendered for filing a petition for waiver of fuel clause regulations.

Comment date: August 29, 1997, in accordance with Standard Paragraph E at the end of this notice.

3. Central and South West Services, Inc.

[Docket No. EL97-48-000]

Take notice that on July 14, 1997, Central and South West Services, Inc., tendered for filing a petition for waiver of fuel clause regulations.

Comment date: August 29, 1997, in accordance with Standard Paragraph E at the end of this notice.

4. The Empire District Electric Company

[Docket Nos. ER97-3488-000, ER97-3489-000, ER97-3490-000, ER97-3491-000, ER97-3492-000, ER97-3495-000, ER97-3496-000, ER97-3499-000, ER97-3501-000, ER97-3502-000, ER97-3504-000, ER97-3505-000, ER97-3506-000, ER97-3507-000, ER97-3508-000, ER97-3509-000, ER97-3510-000, ER97-3511-000, ER97-3512-000, ER97-3513-000, ER97-3514-000, ER97-3516-000, ER97-3518-000, ER97-3519-000, ER97-3520-000, ER97-3521-000, ER97-3522-000]

Take notice that on July 16, 1997, The Empire District Electric Company tendered for filing amendments in the above-referenced dockets.

Comment date: August 25, 1997, in accordance with Standard Paragraph E at the end of this notice.

5. CoEnergy Trading Company

[Docket No. ER96-1040-006]

Take notice that on July 23, 1997, CoEnergy Trading Company filed a notice of change in status to report its participation in a joint venture with a subsidiary of DTE Energy Company to engage in power marketing.

Comment date: August 25, 1997, in accordance with Standard Paragraph E at the end of this notice.

6. The Detroit Edison Company

[Docket No. ER97-324-003]

Take notice that on July 23, 1997, The Detroit Edison Company filed a Notification of Change in Status.

Comment date: August 25, 1997, in accordance with Standard Paragraph E at the end of this notice.

7. New York State Electric & Gas Corporation

[Docket No. ER97-2571-000]

Take notice that on August 1, 1997, New York State Electric & Gas Company tendered for filing an amendment in the above-referenced docket.

Comment date: August 25, 1997, in accordance with Standard Paragraph E at the end of this notice.

8. Central Illinois Light Company

[Docket No. ER97-3568-000]

Take notice that Central Illinois Light Company (CILCO), 300 Liberty Street, Peoria, Illinois 61602, on July 23, 1997, tendered for filing with the Commission a substitute Index of Point-To-Point Transmission Service Customers under its Open Access Transmission Tariff.

CILCO requested an effective date of June 2, 1997.

Copies of the filing were served on the affected customer and the Illinois Commerce Commission.

Comment date: August 25, 1997, in accordance with Standard Paragraph E at the end of this notice.

9. Central Illinois Light Company

[Docket No. ER97-3698-000]

Take notice that on July 14, 1997, Central Illinois Light Company (CILCO), 300 Liberty Street, Peoria, Illinois 61602, tendered for filing with the Commission a substitute Index of Point-To-Point Transmission Service Customers under its Open Access Transmission Tariff and service agreements for four new customers.

CILCO requested an effective date of July 2, 1997.

Copies of the filing were served on all affected customers and the Illinois Commerce Commission.

Comment date: August 25, 1997, in accordance with Standard Paragraph E at the end of this notice.

10. Central Hudson Gas & Electric Company

[Docket No. ER97-3780-000]

Take notice that on July 17, 1997, Central Hudson Gas & Electric Corporation (CHG&E), tendered for a Service Agreement between CHG&E and ProMark Energy. The terms and conditions of service under this Agreement are made pursuant to CHG&E's FERC Open Access Schedule, Original Volume No. 1 (transmission Tariff) filed in compliance with the Commission's Order No. 888 in Docket No. RM95-8-000 and RM94-7-001. CHG&E also has requested waiver of the 60-day notice provision pursuant to 18 CFR Section 35.11.

A copy of this filing has been served on the Public Service Commission of the State of New York.

Comment date: August 25, 1997, in accordance with Standard Paragraph E at the end of this notice.

11. Bruce Demars

[Docket No. ID-3057-000]

Take notice that on July 15, 1997, Bruce Demars (Applicant) tendered for filing an application under Section 305(b) of the Federal Power Act to hold the following positions:

Director: Commonwealth Edison Company

Director: McDermott International, Inc.

Comment date: August 25, 1997, in accordance with Standard Paragraph E at the end of this notice.

12. New England Power Company

[Docket No. OA97-621-000]

Take notice that on July 14, 1997, New England Power Company (NEP) tendered for filing a correction to its

filing letter covering its compliance tariff filed, pursuant to Commission Order No. 888-A. NEP made the filing on behalf of itself and its four retail affiliates.

Comment date: August 25, 1997, in accordance with Standard Paragraph E at the end of this notice.

13. Puget Sound Energy, Inc.

[Docket No. OA97-685-000]

Take notice that on July 14, 1997, Puget Sound Energy, Inc., tendered for filing Puget's proposed Open Access Transmission Tariff pursuant to the Commission's Order No. 888-A.

Comment date: August 25, 1997, 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, DC 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.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 97-21718 Filed 8-14-97; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER97-2822-000, et al.]

Washington Water Power Company, et al.; Electric Rate and Corporate Regulation Filings

August 7, 1997.

Take notice that the following filings have been made with the Commission:

1. Washington Water Power Company

[Docket No. ER97-2822-000]

Take notice that on July 23, 1997 and July 24, 1997, Washington Water Power Company tendered for filing amendments in the above-referenced dockets.

Comment date: August 21, 1997, in accordance with Standard Paragraph E at the end of this notice.

2. Zond Minnesota Development Corporation II; Lake Benton Power Partners, LLC

[Docket No. EC97-47-000]

On August 4, 1997, Zond Minnesota Development Corporation II (Zond Minnesota) and Lake Benton Power Partners, LLC (Lake Benton LLC), P.O. Box 1910, 13000 Jameson Road, Tehachapi, California 93561 submitted for filing an application for approval under Section 203 of the Federal Power Act of the merger of Zond Minnesota with its affiliate Lake Benton LLC. Zond Minnesota and Lake Benton LLC also seek approval of creation of a new entity, Zond Lake Benton, LLC, to be the direct parent company of Lake Benton LLC. Zond Minnesota and Lake Benton LLC request that the Commission act on the application by September 2, 1997. No determination has been made that the submittal constitutes a complete filing.

According to the applicant, Zond Minnesota is developing a wind energy project near Lake Benton, Minnesota that will sell power to Northern States Power Company pursuant to a long-term power purchase agreement. The Commission accepted Zond Minnesota's rates for filing in Zond Development Corp. and Zond Minnesota Development Corp. II, 80 FERC ¶ 61,051 (1997).

Comment date: August 29, 1997, in accordance with Standard Paragraph E at the end of this notice.

3. Public Service Company of Colorado

[Docket No. ER97-3782-000]

Take notice that on July 22, 1997, Public Service Company of Colorado, tendered for filing a Service Agreement for Non-Firm Point-to-Point Transmission Service between Public Service Company of Colorado and Enron Power Marketing, Inc. Public Service states that the purpose of this filing is to provide Non-Firm Point-to-Point Transmission Service in

accordance with its Open Access Transmission Service Tariff.

Comment date: August 21, 1997, in accordance with Standard Paragraph E at the end of this notice.

4. Public Service Company of Colorado

[Docket No. ER97-3783-000]

Take notice that on July 22, 1997, Public Service Company of Colorado, tendered for filing an Umbrella Service Agreement for Firm Point-to-Point Transmission Service between Public Service Company of Colorado and Public Service Company of Colorado—Wholesale Merchant Function. Public Service states that the purpose of this filing is to provide Firm Point-to-Point Transmission Service in accordance with its Open Access Transmission Service Tariff.

Comment date: August 21, 1997, in accordance with Standard Paragraph E at the end of this notice.

5. Public Service Company of Colorado

[Docket No. ER97-3784-000]

Take notice that on July 22, 1997, Public Service Company of Colorado, tendered for filing a Service Agreement for Non-Firm Point-to-Point Transmission Service between Public Service Company of Colorado and PacifiCorp. Public Service states that the purpose of this filing is to provide Non-Firm Point-to-Point Transmission Service in accordance with its Open Access Transmission Service Tariff.

Comment date: August 21, 1997, in accordance with Standard Paragraph E at the end of this notice.

6. Pacific Gas and Electric Company

[Docket No. ER97-3786-000]

Take notice that on July 21, 1997, Pacific Gas and Electric Company (PG&E), tendered for filing; (1) An agreement dated as of July 7, 1997, by and between PG&E and the Duke Louis Dreyfus, LLC. (Duke) entitled Service Agreement for Firm Point-to-Point Transmission Service (Service Agreement); and (2) a request for termination of this Service Agreement.

The Service Agreement was entered into for the purpose of firm point-to-point transmission service for 25 MW of power delivered to Duke at PG&E's Midway Substation. The effective date of termination is either the requested date shown below or such other date the Commission deems appropriate for termination.

Service agreement date	Term	Requested effective date for termination
July 7, 1997—Service Agreement No. _____ under FERC Electric Tariff, Original Volume No. 3.	July 1, 1997 thru July 31, 1997	July 31, 1997.

Copies of this filing have been served upon the California Public Utilities Commission and Duke.

Comment date: August 21, 1997, in accordance with Standard Paragraph E at the end of this notice.

7. Cinergy Services, Inc.

[Docket No. ER97-3787-000]

Take notice that on July 21, 1997, Cinergy Services, Inc. (Cinergy), tendered for filing a service agreement under Cinergy's Open Access Transmission Service Tariff (the Tariff) entered into between Cinergy and Citizens Power Sales (Citizens).

Cinergy and Citizens are requesting an effective date of July 17, 1997.

Comment date: August 21, 1997, in accordance with Standard Paragraph E at the end of this notice.

8. Anker Power Services, Inc.

[Docket No. ER97-3788-000]

Take notice that on July 21, 1997, Anker Power Services, Inc. (Anker Power), tendered for filing with the Federal Energy Regulatory Commission (Commission) Anker Power Services, Inc., FERC Rate Schedule No. 1 which permits Anker Power to make sales of capacity and energy at market-based rates.

Comment date: August 21, 1997, in accordance with Standard Paragraph E at the end of this notice.

9. Florida Power Corporation

[Docket No. ER97-3789-000]

Take notice that on July 21, 1997, Florida Power Corporation (Florida Power), tendered for filing a service agreement providing for non-firm point-to-point service to Southern Energy Trading and Marketing, Inc. (Southern Energy) pursuant to its open access transmission tariff. Florida Power requests that the Commission waive its notice of filing requirements and allow the agreement to become effective on July 22, 1997.

Comment date: August 21, 1997, in accordance with Standard Paragraph E at the end of this notice.

10. Cinergy Services, Inc.

[Docket No. ER97-3790-000]

Take notice that on July 21, 1997, Cinergy Services, Inc. (Cinergy), tendered for filing on behalf of its operating companies, The Cincinnati

Gas & Electric Company (CG&E) and PSI Energy, Inc. (PSI), a Power Purchase Agreement, dated March 14, 1997 between Cinergy, CG&E, PSI and Energy Services, Inc. (ESI).

The Power Purchase Agreement provides for sale on a market basis.

Cinergy and ESI have requested an effective date of one day after this initial filing of the Power Purchase Agreement.

Copies of the filing were served on Energy Services, Inc., Washington Utilities and Transportation Commission, the Kentucky Public Service Commission, the Public Utilities Commission of Ohio and the Indiana Utility Regulatory Commission.

Comment date: August 21, 1997, in accordance with Standard Paragraph E at the end of this notice.

11. Consolidated Edison Company of New York, Inc.

[Docket No. ER97-3791-000]

Take notice that on July 21, 1997, Consolidated Edison Company of New York, Inc. (Con Edison), tendered for filing, pursuant to its FERC Electric Tariff Rate Schedule No. 2, a service agreement for Long Island Lighting Company to purchase electric capacity and energy pursuant to the negotiated rates, terms, and conditions.

Con Edison states that a copy of this filing has been served by mail upon Long Island Lighting Company.

Comment date: August 21, 1997, in accordance with Standard Paragraph E at the end of this notice.

12. Cinergy Services, Inc.

[Docket No. ER97-3792-000]

Take notice that on July 21, 1997, Cinergy Services, Inc. (Cinergy), tendered for filing on behalf of its operating companies, The Cincinnati Gas & Electric Company (CG&E) and PSI Energy, Inc. (PSI), a Power Purchase Agreement, dated March 14, 1997 between Cinergy, CG&E, PSI and Energy Services, Inc. (ESI).

The Power Purchase Agreement provides for sale on a market basis.

Cinergy and ESI have requested an effective date of one day after this initial filing of the Power Purchase Agreement.

Copies of the filing were served on Energy Services, Inc., Washington Utilities and Transportation Commission, the Kentucky Public Service Commission, the Public Utilities

Commission of Ohio and the Indiana Utility Regulatory Commission.

Comment date: August 21, 1997, in accordance with Standard Paragraph E at the end of this notice.

13. Cinergy Services, Inc.

[Docket No. ER97-3793-000]

Take notice that on July 21, 1997, Cinergy Services, Inc. (Cinergy), tendered for filing a service agreement under Cinergy's Open Access Transmission Service Tariff (the Tariff) entered into between Cinergy and Public Service Electric and Gas Company (PSEG).

Cinergy and PSEG are requesting an effective date of July 17, 1997.

Comment date: August 21, 1997, in accordance with Standard Paragraph E at the end of this notice.

14. Cinergy Services, Inc.

[Docket No. ER97-3794-000]

Take notice that on July 21, 1997, Cinergy Services, Inc. (Cinergy), tendered for filing a service agreement under Cinergy's Open Access Transmission Service Tariff (the Tariff) entered into between Cinergy and Tennessee Power Company (Tennessee).

Cinergy and Engelhard are requesting an effective date of July 17, 1997.

Comment date: August 21, 1997, in accordance with Standard Paragraph E at the end of this notice.

15. Cinergy Services, Inc.

[Docket No. ER97-3795-000]

Take notice that on July 21, 1997, Cinergy Services, Inc. (Cinergy), tendered for filing a service agreement under Cinergy's Open Access Transmission Service Tariff (the Tariff) entered into between Cinergy and American Energy Solutions, Inc. (American).

Cinergy and American are requesting an effective date of July 17, 1997.

Comment date: August 21, 1997, in accordance with Standard Paragraph E at the end of this notice.

16. Consolidated Edison Company of New York, Inc.

[Docket No. ER97-3796-000]

Take notice that on July 21, 1997, Consolidated Edison Company of New York, Inc. (Con Edison), tendered for filing, pursuant to its FERC Electric Tariff Rate Schedule No. 2, a service

agreement for PanEnergy Trading and Marketing, L.L.C., to purchase electric capacity and energy pursuant to the negotiated rates, terms, and conditions.

Con Edison states that a copy of this filing has been served by mail upon PanEnergy Trading and Marketing, L.L.C.

Comment date: August 21, 1997, in accordance with Standard Paragraph E at the end of this notice.

17. Consolidated Edison Company of New York, Inc.

[Docket No. ER97-3797-000]

Take notice that on July 21, 1997, Consolidated Edison Company of New York, Inc. (Con Edison), tendered for filing a service agreement to provide non-firm transmission service pursuant to its Open Access Transmission Tariff to New York State Electric & Gas Corporation.

Con Edison states that a copy of this filing has been served by mail upon New York State Electric & Gas Corporation.

Comment date: August 21, 1997, in accordance with Standard Paragraph E at the end of this notice.

18. Wisconsin Public Service Corporation

[Docket No. ER97-3799-000]

Take notice that on July 21, 1997, Wisconsin Public Service Corporation (WPSC), tendered for filing an executed Transmission Service Agreement between WPSC and Wisconsin Power & Light Company. The Agreement provides for transmission service under the Open Access Transmission Service Tariff, FERC Original Volume No. 11.

Comment date: August 21, 1997, in accordance with Standard Paragraph E at the end of this notice.

19. Illinois Power Company

[Docket No. ER97-3800-000]

Take notice that on July 21, 1997, Illinois Power Company (Illinois Power), 500 South 27th Street, Decatur, Illinois 62526, tendered for filing a Power Sales Tariff, Service Agreement under which Williams Energy Services Company will take service under Illinois Power Company's Power Sales Tariff. The agreements are based on the Form of Service Agreement in Illinois Power's tariff.

Illinois Power has requested an effective date of July 1, 1997.

Comment date: August 21, 1997, in accordance with Standard Paragraph E at the end of this notice.

20. Kansas City Power & Light Company

[Docket No. ER97-3801-000]

Take notice that on July 21, 1997, Kansas City Power & Light Company (KCPL), tendered for filing a Service Agreement dated July 17, 1997, between KCPL and Sonat Power Marketing L.P. KCPL proposes an effective date of July 17, 1997, and requests waiver of the Commission's notice requirement. This Agreement provides for Non-Firm Power Sales Service.

In its filing, KCPL states that the rates included in the above-mentioned Service Agreement are pursuant to KCPL's compliance filing in Docket No. ER94-1045.

Comment date: August 21, 1997, in accordance with Standard Paragraph E at the end of this notice.

21. TransAlta Enterprises Corporation

[Docket No. ER97-3802-000]

Take notice that on July 21, 1997, TransAlta Enterprises Corporation, tendered for filing a Notice of Succession of all its jurisdictional rate schedules and supplements thereto by TransAlta Energy Marketing Corp.

Comment date: August 21, 1997, in accordance with Standard Paragraph E at the end of this notice.

22. UtiliCorp United Inc.

[Docket No. ES97-40-000]

Take notice that on July 29, 1997, UtiliCorp United Inc. (Applicant) filed an application seeking an order under Section 204(a) of the Federal Power Act authorizing the Applicant to issue, from time to time during a two-year period, unsecured notes and other obligations, including financial guarantees of securities issued by subsidiaries and affiliates up to and including \$400,000,000 in the aggregate at any one time outstanding, for periods of time not exceeding twelve months after issuance.

Comment date: September 2, 1997, in accordance with Standard Paragraph E at the end of this notice.

23. In the Matter of MDU Resources Group, Inc.

[Docket No. ES97-41-000]

Take notice that on July 31, 1997, MDU Resources Group, Inc. (Applicant), filed an application with the Federal Energy Regulatory Commission, pursuant to Section 204 of the Federal Energy Power Act (Act), seeking an Order authorizing the issuance of not to exceed \$45,000,000 aggregate principal amount of one or more series of its First Mortgage Bonds, secured medium term notes, and/or Senior Notes.

The securities are proposed to be issued from time to time over a two-year period.

Comment date: September 2, 1997, in accordance with Standard Paragraph E at the end of this notice.

24. In the Matter of MDU Resources Group, Inc.

[Docket No. ES97-42-000]

Take notice that on July 31, 1997, MDU Resources Group, Inc. (Applicant), filed an application with the Federal Energy Regulatory Commission, pursuant to Section 204 of the Federal Power Act (Act), seeking an Order to authorize, over a five-year period, the issuance of up to \$40,000,000 of short-term debt, at any one time, in the form of promissory notes with maturities of one year or less.

Comment date: September 2, 1997, in accordance with Standard Paragraph E at the end of this notice.

25. Jersey Central Power & Light Company; Metropolitan Edison Co.; Pennsylvania Electric Co.

[Docket No. OA97-692-000]

Take notice that on July 14, 1997, Jersey Central Power & Light Company, Metropolitan Edison Company and Pennsylvania Electric Company (doing business as GPU Energy) made a filing in compliance with the Commission's Order No. 888-A.

Comment date: August 21, 1997, in accordance with Standard Paragraph E at the end of this notice.

26. Cambridge Electric Light Company, Commonwealth Electric Company

[Docket No. OA97-693-000]

Take notice that on July 14, 1997, Cambridge Electric Light Company and Commonwealth Electric Company tendered for filing copies of their revised Standards of Conduct in compliance with Order No. 889-A.

Comment date: August 21, 1997, in accordance with Standard Paragraph E at the end of this notice.

27. Union Electric Company

[Docket No. OA97-695-000]

Take notice that on July 14, 1997, Union Electric Company tendered for filing a revised open access transmission tariff in accordance with FERC Order No. 888-A. Union Electric states that the revised tariff reflects changes to the non-rate terms and conditions of the generic form of open access transmission tariff prescribed in Order No. 888-A and rate-related changes that were previously included in an Offer of Settlement that was filed in this proceeding on March 28, 1997.

Comment date: August 21, 1997, in accordance with Standard Paragraph E at the end of this notice.

28. Vermont Electric Power Company, Inc.

[Docket No. OA97-696-000]

Take notice that on July 14, 1997, Vermont Electric Power Company, Inc. (VELCO) tendered for filing a Local Open Access Transmission Service Tariff in compliance with the Commission's Order No. 888-A, FERC Stats. & Regs. Preambles ¶ 31,048 (1997). VELCO requests an effective date of July 14, 1997.

VELCO states that it has served a copy of its compliance filing on each of the Vermont distribution utilities served by VELCO, intervenors in VELCO's open access transmission tariff proceedings in Docket No. OA97-7-000 and ER97-1930-000, the Vermont Department of Public Service, the Vermont Public Service Board and New Hampshire Electric Cooperative, Inc.

Comment date: August 21, 1997, in accordance with Standard Paragraph E at the end of this notice.

29. Florida Power Corporation

[Docket No. ER97-3798-000]

Take notice that on July 21, 1997, Florida Power Corporation (Florida Power), tendered for filing a service agreement providing for non-firm point-to-point service to Morgan Stanley Capital Group, Inc. (Morgan Stanley), pursuant to its open access Transmission Tariff. Florida Power requests that the Commission waive its notice of filing requirements and allow the agreement to become effective on July 22, 1997.

Comment date: August 21, 1997, 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.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 97-21608 Filed 8-14-97; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 1494-119]

Grand River Dam Authority; Notice of Availability of Final Environmental Assessment

August 11, 1997.

A final environmental assessment (EA) is available for public review. The final EA analyzes the environmental impacts of an application by Grand River Dam Authority (licensee) to grant a permit to Mr. Larry Herrelson of Patricia Island Estates. The permit would allow Mr. Herrelson to excavate about 25,880 cubic yards of sediment from 9 coves on project lands for future recreational access. Patricia Island Estates is a planned residential community being developed in the Patricia Island portion of Grand Lake, Delaware County, near the town of Grove, Oklahoma. The final EA finds that the application to grant the permit would not constitute a major federal action significantly affecting the quality of the human environment. The Pensacola Project is on the Grand River, in Craig, Delaware, Mayes, and Ottawa Counties, Oklahoma.

The final EA was written by staff in the Office of Hydropower Licensing, Federal Energy Regulatory Commission. Copies of the final EA can be obtained by calling the Commission's Public Reference Room at (202) 208-1371.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 97-21615 Filed 8-14-97; 8:45 am]

BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

[ER-FRL-5483-3]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared July 21, 1997 Through July 25, 1997 pursuant to the Environmental Review Process (ERP), under Section 309 of the Clean Air Act and Section 102(2)(c) of the National Environmental

Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 564-7167.

An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 4, 1997 (62 FR 16154).

Draft EISs

ERP No. D-DOI-K40222-TT Rating EO2, Palau Compact Road Construction, Implementation, Funding, Republic of Palau, Babeldaob Island, Trust Territory of the Pacific Islands.

Summary: EPA expressed environmental objections due to wetland and water quality impacts associated with developing quarry or coral dredge sites. EPA requested additional information to demonstrate compliance with the Clean Water Act 404(b)(1) Guidelines including mitigation to compensate for the fill placed in 21 acres of wetlands.

ERP No. D-NPS-E61038-TN Rating LO, Stones River National Battlefield General Management Plan and Development Concept Plan, Implementation, Ruthford County, TN.

Summary: EPA expressed lack of objections for the proposed action.

ERP No. D-OSM-A01102-00 Rating EC2, Valid Existing Rights—Proposed Revisions to the Permanent Program Regulations Implementing Section 522(E) of the Surface Mining Control and Reclamation Act of 1977 and Proposed Rulemaking Clarifying the Applicability of Section 522(E) to Subsidence from Underground Mining.

Summary: EPA expressed environmental concerns with the air quality analysis, potential adverse impacts to water quality and mitigation measures, adequate bonding, design and reclamation issues, indirect and cumulative impacts and environmental justice and suggests these be addressed in the final EIS.

Final EISs

ERP No. F-UAF-K11076-CA, Airborne Laser (ABL) Phase Program Definition and Risk Reduction Phase, Proposed Locations: Home Base Edwards Air Force Base; Diagnostic Test Range-White Sands Missile Range, NM; and Expanded Area Test Range-Western Range (Vandenberg Air Force Base and Point Mugu Naval Air Warfare Center Weapons Division), CA and NM.

Summary: EPA previous concerns have been addressed, therefore EPA had no objection to the action as proposed.

Dated: August 12, 1997.

William D. Dickerson,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 97-21723 Filed 8-14-97; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[ER-FRL-5483-2]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564-7167 OR (202) 564-7153.

Weekly receipt of Environmental Impact Statements

Filed August 04, 1997 Through August 08, 1997 Pursuant to 40 CFR 1506.9.

EIS No. 970302, Final EIS, DOE, ID, Nez Perce Tribal Hatchery Program, Implementation, Restore Chenook Salmon to the Clearwater River Subbasin, Snake River, Idaho, Due: September 15, 1997, Contact: Leslie Kelleher (503) 230-7692.

EIS No. 970303, Draft EIS, FHW, NY, NY-120/22 Reconstruction Corridor, from Exits 2 and 3 on I-684 and Old Post Road (PIN-8130.75), Funding, COE Section 10 and 404 Permits, Town of North Castle, Westchester County, NY, Due: September 29, 1997, Contact: H.J. Brown (518) 431-4127.

EIS No. 970304, Final EIS, COE, KY, TN, Fort Campbell Rail Connector, Construction between the Government-Owned Line Railroad and CSX Line, Hopkinsville and Clarkville, Christian Co., KY and Montgomery and Stewart Counties, TN, Due: September 15, 1997, Contact: William Ray Haynes (502) 582-6475.

EIS No. 970305, Final EIS, AFS, ID, White Pine Creek Salvage Timber Sale, Implementation, Clearwater National Forest, Palouse Ranger District, Benewah and Latah Counties, ID, Due: September 15, 1997, Contact: Suzanne Lay (208) 875-1131.

EIS No. 970306, Draft Supplement, FHW, PA, US 222 Corridor Design Location Study, Improvements from Breingsville to the I-78 Interchange, Funding, New and Updated Information, Lower and Upper Macungie Township, Lehigh County, PA, Due: September 30, 1997, Contact: Ronald W. Carmichael (717) 780-3461.

EIS No. 970307, Draft Supplement, AFS, MT, Helena National Forest and Elkhorn Mountain portion of the Deerlodge National Forest Land and

Resource Management Plan, Updated Information on Oil and Gas Leasing, Implementation, several counties, MT, Due: September 29, 1997, Contact: Thomas Anderson (406) 449-5201.

EIS No. 970308, Final Supplement, AFS, AK, Kensington Venture Underground Gold Mine Project, Development, Construction and Operation, Operating Plan Approval, NPDES, Section 10 and 404 Permits, Tongass National Forest, Sherman Creek, City of Juneau, AK, Due: September 15, 1997, Contact: Roger Birk (907) 586-8800.

EIS No. 970309, Draft EIS, USA, CO, United States Army Garrison, Fitzsimons (Formerly Fitzsimons Army Medical Center) Disposal and Reuse for BRAC-95, Implementation, City of Aurora, Denver County, CO, Due: September 29, 1997, Contact: Gene Sturm (402) 221-4886.

EIS No. 970310, Draft EIS, BLM, OR, Beatty Butte Allotment Management Plan, Implementation, Lakeview District, Hart Mountain National Antelope Refuge, Lake and Harney Counties, OR, Due: October 15, 1997, Contact: Paul Whitman (541) 947-2177.

EIS No. 970311, Final EIS, FTA, NY, Wassaic Extension Project, Expand Metro-North, Funding and Right-of-Way, Dutchess and Litchfield Counties, NY, Due: September 15, 1997, Contact: Anthony G. Carr (212) 264-8973.

EIS No. 970312, Final EIS, FAA, NC, ADOPTION—Camp Lejeune Marine Corps Base Camp, Expansion and Realignment for Additional Training Needs, Implementation, Onslow County, NC, Due: September 15, 1997, Contact: Mary Summer (202) 267-9183.

The US Department of Transportation's Federal Aviation Administration has adopted the US Marine Corp's FEIS #910144 filed with the US Environmental Protection Agency on 05-07-91, FAA was not a Cooperating Agency on this project. Recirculation of the document is necessary under Section 1506.3(b) of the Council on Environmental Quality Regulations.

Amended Notices

EIS No. 970296, Draft EIS, NPS, HI, Ala Kahakai "Trail By the Sea" National Trail Study, Implementation, Hawaii Island, Hawaii County, HI, Due: October 07, 1997, Contact: Meredith Kaplan (415) 427-1438.

Published FR-08-08-97—Correction to the Agency's Bureau Code from BLM to NPS.

Dated: August 12, 1997.

William D. Dickerson,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 97-21724 Filed 8-14-97; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[OPP-00498; FRL-5731-6]

Pesticide Spray Drift Task Force; Data Review Workshop

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA's Office of Pesticide Programs (OPP) is giving notice of a public workshop for the Spray Drift Task Force Data Review.

DATES: The workshop will be held on Thursday, September 11, 1997, from 8:30 a.m. to 5:00 p.m. and Friday, September 12, 1997, from 8:30 a.m. to noon.

ADDRESSES: The meeting will be held at: the Days Inn, 2000 Jefferson Davis Highway, Arlington, Virginia.

FOR FURTHER INFORMATION CONTACT: By mail: Arnet Jones (7507C), Nelson Thurman (7507C), or Leo LaSota (7509C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Telephone numbers and e-mail addresses: Arnet Jones, (703) 305-7416, jones.arnet@epamail.epa.gov; Nelson Thurman, (703) 308-0465, thurman.nelson@epamail.epa.gov; and Leo LaSota, (703) 305-7402, LaSota.leo@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: The chief purpose of the workshop is to discuss the scientific aspects of the aerial field studies and supporting data (including atomization, physical properties studies) which the Pesticide Spray Drift Task Force (SDTF) submitted to EPA. The participants in the workshop will include OPP's Environmental Effects and Fate Division, EPA's Office of Research and Development, USDA's Agricultural Research Service, Environment Canada, and California EPA's Department of Pesticide Regulation, all of which have prepared reviews of the aerial field data and supporting studies. In addition to these organizations, three independent scientists who have prepared reviews under contract to OPP will also make presentations. A list of studies submitted by the SDTF is available from one of the contacts listed above.

The workshop will focus on the technical reviews by the invited participants. However, outside observers (interested parties who were not part of the technical review) will have an opportunity to comment on scientific and technical issues related to the studies after the initial presentations on the morning of the 11th. Additional comments may also be made on the morning of the 12th, after the reviewers have discussed the issues raised on the first morning and have prepared a summary of their responses. A demonstration of the AgDRIFT Model will be given the afternoon of the 11th. The SDTF aerial data and the results of this peer review workshop will be discussed with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel at their December 1977 meeting.

List of Subjects

Environmental protection, Pesticides.
Dated: August 12, 1997.

Anne E. Lindsay,

*Director, Field and External Affairs Division,
Office of Pesticide Programs.*

[FR Doc. 97-21807 Filed 8-14-97; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

[OPP-30416A; FRL-5730-2]

Ecoval Technologies Inc.; Approval of a Pesticide Product Registration

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces Agency approval of an application to register the pesticide product Eco-N Select 1.6, containing an active ingredient not included in any currently registered product pursuant to the provisions of section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

FOR FURTHER INFORMATION CONTACT: By mail: Sheila A. Moats, Regulatory Action Leader, Biochemicals Branch, Biopesticides and Pollution Prevention Division (7501W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. CS5-W39, Westfield Building North Tower, 2800 Crystal Drive, Arlington, VA 22202, (703) 308-1259; e-mail: moats.sheila@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

Electronic Availability: Electronic copies of this document and the Fact Sheet are available from the EPA home page at the Environmental Sub-Set entry for this document under "Regulations" (<http://www.epa.gov/fedrgstr/>).

EPA issued a notice, published in the **Federal Register** of July 10, 1996 (61 FR 36369; FRL-5383-5), which announced that Ecoval Technologies Inc., 3600 boul. du Tricentenaire Pointe-aux-Temples, Quebec H1B 5M8, had submitted an application to register the pesticide product Eco-N Select 1.6 (EPA File Symbol 069836-R), containing the active ingredient acetic acid: ethanoic acid [C₂H₄O₂] at 25 percent, an active ingredient not included in any currently registered product.

The application was approved on February 13, 1997, as Eco-N Select 1.6 for non-selective control of herbaceous broadleaf and grass weeds in non-crop, right-of-way, and industrial land sites (EPA Registration Number 069831-1).

The Agency has considered all required data on risks associated with the proposed use of acetic acid: ethanoic acid [C₂H₄O₂], and information on social, economic, and environmental benefits to be derived from use. Specifically, the Agency has considered the nature of the chemical and its pattern of use, application methods and rates, and level and extent of potential exposure. Based on these reviews, the Agency was able to make basic health safety determinations which show that use of acetic acid: ethanoic acid [C₂H₄O₂] when used in accordance with widespread and commonly recognized practice, will not generally cause unreasonable adverse effects to the environment.

More detailed information on this registration is contained in an EPA Pesticide Fact Sheet on acetic acid: ethanoic acid [C₂H₄O₂].

A copy of these fact sheets, which provide a summary description of the pesticides, use patterns and formulations, science findings, and the Agency's regulatory position and rationale, may be obtained from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

In accordance with section 3(c)(2) of FIFRA, a copy of the approved label, the list of data references, the data and other scientific information used to support registration, except for material specifically protected by section 10 of FIFRA, are available for public inspection in the Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection

Agency, Rm. 1132, CM #2, Arlington, VA 22202 (703-305-5805). Requests for data must be made in accordance with the provisions of the Freedom of Information Act and must be addressed to the Freedom of Information Office (A-101), 401 M St., SW., Washington, D.C. 20460. Such requests should: (1) Identify the product name and registration number and (2) specify the data or information desired.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Pesticides and pests, Product registration.

Dated: August 6, 1997.

Janet L. Andersen,

*Director, Biopesticides and Pollution
Prevention Division, Office of Pesticide
Programs.*

[FR Doc. 97-21692 Filed 8-14-97; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

[FRL-5875-3]

Notice of Proposed Agreement and Covenant Not to Sue, Hastings Ground Water Contamination Superfund Site, Colorado Avenue Subsite

Notice of Proposed Agreement and Covenant Not to Sue Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended, 42 U.S.C. Section 101 *et seq.*, Hastings Ground Water Contamination Superfund Site, Colorado Avenue Subsite, Hastings, Nebraska.

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Notice of proposed agreement and covenant not to sue, Hastings Ground Water Contamination Superfund Site, Colorado Avenue Subsite.

SUMMARY: Notice is hereby given that a proposed agreement and covenant not to sue regarding property which the City of Hastings intends to purchase at the Hastings Ground Water Contamination Superfund Site, Colorado Avenue Subsite, was signed by the United States Environmental Protection Agency (EPA) on July 3, 1997 and by the United States Department of Justice on July 31, 1997. The property that is the subject of this agreement is the portion of the Union Pacific Right of Way that is located at the Subsite (Property). The Subsite is bounded by Kansas Avenue, South Street, Pine Avenue, and the Burlington

Northern Santa Fe Railway Company tracks in Hastings, Nebraska.

DATES: EPA will receive comments for a period of September 15, 1997.

ADDRESSES: Comments should be addressed to Audrey Asher, Senior Assistant Regional Counsel, United States Environmental Protection Agency, Region VII, 726 Minnesota Avenue, Kansas City, KS 66101 and should refer to *Hastings Ground Water Contamination Superfund Site, Colorado Avenue Subsite Agreement and Covenant Not to Sue*.

The proposed agreement and covenant not to sue may be examined or obtained in person or by mail at the office of the United States Environmental Protection Agency, Region VII, 726 Minnesota Avenue, Kansas City, KS 66101 (913) 551-7255. In requesting a copy, please refer to the referenced case and enclose a check in the amount of \$10.25 (25 cents per page reproduction costs), payable to the United States Environmental Protection Agency.

SUPPLEMENTARY INFORMATION: Soil and ground water at the Colorado Avenue Subsite are contaminated with hazardous substances attributable to historic manufacturing operations at a manufacturing facility located at 108 S. Colorado Avenue. The proposed agreement concerns Property located east of the 108 S. Colorado Avenue facility.

EPA has issued unilateral administrative orders to former and current owner/operators of the 108 S. Colorado Avenue facility, requiring these parties to design and implement a Source Control Remedial Action and a Ground Water Remedial Action.

Under the proposed agreement and covenant not to sue, the City of Hastings agrees to provide access to the Property for implementation of response actions at the Subsite and to reserve a portion of the Property for the installation of industrial water lines to be used for response activities. In exchange for the access, the United States grants a limited covenant not to sue, intended to release the City from liability which otherwise would stem from ownership of the Property.

Dated: August 6, 1997.

Martha R. Steincamp,

Acting Regional Administrator, United States Environmental Protection Agency, Region VII.

[FR Doc. 97-21700 Filed 8-14-97; 8:45 am]

BILLING CODE 6560-50-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL-5875-2]

Proposed Administrative Order On Consent; Reclaim Barrel Site, Salt Lake County, UT

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed section 122(g)(4) *de minimis* settlements.

SUMMARY: In accordance with the requirements of section 122(g)(4) of the Comprehensive Environmental Response, Compensation, and Liability Act, as amended (CERCLA), 42 U.S.C. 9601 *et seq.*, notice is hereby given of proposed *de minimis* settlement agreements under section 122(g)(4), 42 U.S.C. 9622(g)(4), concerning the Reclaim Barrel Site in Salt Lake County, Utah (the "Site"). The proposed Administrative Orders on Consent (AOC) require the settling parties, identified in the attached table entitled "Settling Parties & Amounts", to pay a total of \$147,784 to resolve their liability for response costs incurred and to be incurred by the United States Environmental Protection Agency ("EPA") in connection with the remediation of the Reclaim Barrel Site.

DATES: Comments must be submitted to EPA on or before September 15, 1997.

ADDRESSES: Comments should be addressed to Matthew Cohn, (8ENF-L), Senior Enforcement Attorney, U.S. Environmental Protection Agency, Region VIII, 999 18th Street, Suite 500, Denver, Colorado 80202-2466, and should refer to: In the Matter of: Reclaim Barrel Site Administrative Settlement Agreement.

FOR FURTHER INFORMATION CONTACT:

Matthew Cohn, (8ENF-L), Senior Enforcement Attorney, U.S. Environmental Protection Agency, Region VIII, 999 18th Street, Suite 500, Denver, Colorado 80202-2466, (303) 312-6853.

SUPPLEMENTARY INFORMATION: Notice of section 122(g)(4), 42 U.S.C. 9622(g)(4), Administrative Order on Consent *De Minimis* Settlements: In accordance with section 122(g)(4) of CERCLA, 42 U.S.C. 9622(g)(4), notice is hereby given that the terms of 42 Administrative Orders on Consent (AOC) for a *de minimis* settlement have been agreed to by the settling parties identified in the attached table.

By the terms of the proposed AOCs, the *de minimis* settling parties will collectively pay \$147,784 to the EPA Hazardous Substance Superfund. In exchange for payment, as provided for by CERCLA, each settling party will receive a covenant not to sue for liability under sections 106 and 107(a) of CERCLA, 42 U.S.C. 9606 and 9607(a), and contribution protection under section 122(g) of CERCLA, 42 U.S.C. 9622(g).

The amount that each individual settling party will pay is directly related to the amount of hazardous substances that party contributed to the Site, including a premium payment related to future response costs. Where adequate proof was provided that drums either did not initially contain hazardous substances or drums were properly cleaned prior to shipment, EPA removed the party from the waste-in list.

U.S. EPA will receive, for a period of thirty (30) days from the date of this publication, comments relating to the proposed administrative *de minimis* settlement agreements.

A generic copy of the proposed AOCs may be obtained in person or by mail from Sharon Abendschan, Enforcement Specialist (ENF-T), Environmental Protection Agency, Region VIII, 999 18th Street, Suite 500, Denver, Colorado 80202-2466, (303) 312-6957. Additional background information relating to the administrative settlement agreement is available for review at the Superfund Records Center at the above address.

Dated: August 7, 1997.

Carol Rushin,

Assistant Regional Administrator, Office of Enforcement, Compliance and Environmental Justice.

SETTLING PARTIES & AMOUNTS

Docket No.	Company name	Payment amount
CERCLA-VIII-97-50	Asphalt Systems	\$816.00
CERCLA-VIII-97-57	Beehive Machinery	680.00
CERCLA-VIII-97-36	Borden/Meadow Gold Dairies, Inc.	2,314.00
CERCLA-VIII-97-14	Cardwell Distributing	12,888.00

SETTLING PARTIES & AMOUNTS—Continued

Docket No.	Company name	Payment amount
CERCLA-VIII-97-51	Central Dist.	816.00
CERCLA-VIII-97-21	Christensen Oil Co.	5,182.00
CERCLA-VIII-97-10	Church & Dwight	19,602.00
CERCLA-VIII-97-52	Color & Abrasive Supply	816.00
CERCLA-VIII-97-35	Community Press	2,314.00
CERCLA-VIII-97-18	Cowboy Oil	6,656.00
CERCLA-VIII-97-19	Firestone	5,636.00
CERCLA-VIII-97-30	Flasher Barricades	2,994.00
CERCLA-VIII-97-63	Gus Paulos Chevrolet	544.00
CERCLA-VIII-97-33	Heckett Multiserv	2,478.00
CERCLA-VIII-97-13	Hutchinson Oil	13,040.00
CERCLA-VIII-97-43	Hydro Engineering	1,252.00
CERCLA-VIII-97-27	Imperial Marble	3,186.00
CERCLA-VIII-97-60	Ivan Walker, Inc.	548.00
CERCLA-VIII-97-39	Jardine Petroleum, Co.	1,648.00
CERCLA-VIII-97-62	KCI Therapeutic	544.00
CERCLA-VIII-97-32	Kemco Oil & Chemicals	2,564.00
CERCLA-VIII-97-68	Landa	408.00
CERCLA-VIII-97-25	LaRoche Ind.	3,512.00
CERCLA-VIII-97-42	Messmer's	1,336.00
CERCLA-VIII-97-37	Miller Gas	2,030.00
CERCLA-VIII-97-56	Monroc	680.00
CERCLA-VIII-97-59	NCR	598.00
CERCLA-VIII-97-31	New Life	2,858.00
CERCLA-VIII-97-12	Raytheon Aircraft Montek, Co.	13,858.00
CERCLA-VIII-97-17	Reichold Chemical	8,412.00
CERCLA-VIII-97-47	Saint-Gobain Corp.	926.00
CERCLA-VIII-97-65	Salt Lake County	490.00
CERCLA-VIII-97-67	SanSegal Sportswear	408.00
CERCLA-VIII-97-40	Sonwil Products, Inc.	1,634.00
CERCLA-VIII-97-23	Strategic Dist.	4,520.00
CERCLA-VIII-97-61	Tabco	544.00
CERCLA-VIII-97-58	Tri-Valley Dist.	646.00
CERCLA-VIII-97-16	Unisys	8,624.00
CERCLA-VIII-97-34	Utah Dept. of Corrections	2,342.00
CERCLA-VIII-97-38	Vacation Village	1,906.00
CERCLA-VIII-97-41	Western Quality Concrete	1,580.00
CERCLA-VIII-97-24	Wright Oil & Tire	3,954.00

[FR Doc. 97-21701 Filed 8-14-97; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL ELECTION COMMISSION**[Notice 1997-13]****Filing Dates for the New York Special Election****AGENCY:** Federal Election Commission.**ACTION:** Notice of Filing Dates for Special Election.**SUMMARY:** New York has scheduled a special election on November 4, 1997, to fill the U.S. House seat in the Thirteenth

Congressional District vacated by Representative Susan Molinari.

Committees required to file reports in connection with the Special General Election on November 4 should file a 12-day Pre-General Election Report on October 23, 1997; a 30-day Post-General Report on December 4, 1997; and a Year-End Report on January 31, 1998.

FOR FURTHER INFORMATION CONTACT:

Ms. Bobby Werfel, Information Division, 999 E Street, N.W., Washington, DC 20463, Telephone: (202) 219-3420; Toll Free (800) 424-9530.

SUPPLEMENTARY INFORMATION: All principal campaign committees of

candidates who participate in the New York Special General Election and all other political committees not filing monthly which support candidates in the Special Election shall file a 12-day Pre-General Report on October 23, 1997, with coverage dates from the close of the last report filed, or the day of the committee's first activity, whichever is later, though October 15, 1997; a Post-General Report on December 4, 1997, with coverage dates from October 16 through November 24, 1997; and a Year-End Report on January 31, 1998, with coverage dates from November 25 through December 31, 1997.

CALENDAR OF REPORTING DATE FOR NEW YORK SPECIAL ELECTION FOR COMMITTEES INVOLVED IN THE SPECIAL GENERAL (11/04/97)

Report	Close of books*	Reg./Cert. mailing date**	Filing date
Pre-General	10/15/97	10/20/97	10/23/97
Post-General	11/24/97	12/04/97	12/04/97

CALENDAR OF REPORTING DATE FOR NEW YORK SPECIAL ELECTION FOR COMMITTEES INVOLVED IN THE SPECIAL GENERAL
(11/04/97)—Continued

Report	Close of books*	Reg./Cert. mailing date**	Filing date
Year-End	12/31/97	01/31/98	01/31/98

*The period begins with the close of books of the last report filed by the committee. If the committee has filed no previous reports, the period begins with the date of the committee's first activity.

**Reports sent by registered or certified mail must be postmarked by the mailing date; otherwise, they must be received by the filing date.

Dated: August 12, 1997.

John Warren McGarry,

Chairman, Federal Election Commission.

[FR Doc. 97-21656 Filed 8-14-97; 8:45 am]

BILLING CODE 6715-01-M

Board of Governors of the Federal Reserve System, August 12, 1997.

William W. Wiles,

Secretary of the Board.

[FR Doc. 97-21729 Filed 8-14-97; 8:45 am]

BILLING CODE 6210-01-F

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. The notices also will 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 August 29, 1997.

A. Federal Reserve Bank of Atlanta
(Lois Berthaume, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303-2713:

1. *Bob Maurice Prillaman and Lillias B. Prillaman*, Marietta, Georgia; to acquire 10.36 percent of the voting shares of Independent Bancshares, Inc., Powder Springs, Georgia.

B. Federal Reserve Bank of Chicago
(Philip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690-1413:

1. *Steven A. Grell*, Bovee Investment Trust, Michael R. Bovee, Trustee, Bruce Tamisiea, Bruce Nystrom, Gary Grave, John M. Cotton, and David M. Hultgren, all of Spencer, Iowa, acting in concert, to acquire a total of 10.72 percent of the voting shares of Albert City Bankshares, Inc., Albert City, Iowa, and thereby indirectly acquire Albert City Savings Bank, Albert City, Iowa, and The Citizens State Bank, Marathon, Iowa.

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Submission to OMB Under Delegated Authority

Background

Notice is hereby given of the final approval of proposed information collections by the Board of Governors of the Federal Reserve System (Board) under OMB delegated authority, as per 5 CFR 1320.16 (OMB Regulations on Controlling Paperwork Burdens on the Public). The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

FOR FURTHER INFORMATION CONTACT:

Chief, Financial Reports Section—Mary M. McLaughlin—Division of Research and Statistics, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202-452-3829)
OMB Desk Officer—Alexander T. Hunt—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, DC 20503 (202-395-7860)

Final approval under OMB delegated authority of the extension for three years, with revision, of the following reports:

1. *Report title:* Commercial Bank Report of Consumer Credit
Agency form number: FR 2571
OMB Control number: 7100-0080
Effective Date: Reporting month ending September 30, 1997
Frequency: Monthly
Reporters: Commercial banks
Annual reporting hours: 2,475
Estimated average hours per response: 0.55

Number of respondents: 375

Small businesses are not affected.

General description of report: This information collection is voluntary (12 U.S.C. 225a and 248(a)(2)) and is given confidential treatment under the Freedom of Information Act (5 U.S.C. 552(b)(4)).

Abstract: The FR 2571 collects information on consumer credit outstanding, by type of credit (automobile loans, revolving credit, and all other consumer credit), as of the last business day of the month, as well as three items on outstanding balances underlying securitized loan sales. The information, together with information obtained from other Federal Reserve reports and from secondary sources, is used to construct information on consumer credit for current analysis for monetary policy purposes. The following initially proposed revisions were approved:

1. reduce the authorized panel size from 400 to 375 commercial banks;
2. redefine loans to purchase automobiles (item 1 and Securitized Consumer Loans item 1.a) to include loans to purchase light trucks for personal use;
3. eliminate the two annual items, Total noninstallment credit (item 5) and Total (item 6);
4. eliminate the distinction between installment and noninstallment debt. (Items 1, 3, and 4 and Securitized Consumer Loans item 1.c were redefined to include both installment and noninstallment credit).

In addition, the FR 2571 was revised to reflect a recent change to the Reports of Income and Condition (FFIEC 031-032; OMB No. 7100-0036; Call Reports), Schedule RC-L, memorandum item 5. In order to maintain the definitional relationship between the Call Report and FR 2571, the Federal Reserve revised FR 2571, Securitized Consumer Loans items 1.a through 1.c, to include all loans that have been securitized and sold, whether sold with or without recourse; previously, only loans securitized and sold without recourse were reported in these FR 2571 items.

2. *Report titles:* Quarterly Report of Interest Rates on Selected Direct

Consumer Installment Loans; Quarterly Report of Credit Card Plans
Agency form numbers: FR 2835, FR 2835a

OMB Control number: 7100-0085
Effective Date: The November 1997 reporting period

Frequency: Quarterly
Reporters: Commercial banks
Annual reporting hours: 90 (FR 2835), 200 (FR 2835a)
Estimated average hours per response: 0.15 (FR 2835), 0.50 (FR 2835a)
Number of respondents: 150 (FR 2835), 100 (FR 2835a)

Small businesses are not affected.

General description of reports: This information collection is voluntary (12 U.S.C. 248(a)(2)). The FR 2835 is not given confidential treatment, and the FR 2835a is given confidential treatment under the Freedom of Information Act (5 U.S.C. 552(b)(4)).

Abstract: The FR 2835 collects the most common interest rate (largest dollar volume of loans) charged at a sample of commercial banks on two types of consumer loans made in a given week each quarter: new auto loans and other loans for consumer goods and personal expenditures. The FR 2835a collects two measures of average credit card interest rates from a sample of commercial banks. The information, together with information obtained from other Federal Reserve reports and from secondary sources, is used to construct information on consumer credit for current analysis for monetary policy purposes. On the FR 2835, the Federal Reserve redefined interest rates on loans for new automobiles (item 1) to include rates on loans to purchase light trucks for personal use and reduced the authorized panel size from 175 to 150 commercial banks. On the FR 2835a, the Federal Reserve reduced the authorized panel size from 150 to 100 commercial banks.

3. *Report title:* Monthly Survey of Industrial Electricity Use
Agency form numbers: FR 2009a, FR 2009b

OMB Control number: 7100-0057
Effective Date: Reporting month ending October 31, 1997

Frequency: Monthly
Reporters: Public and privately owned electric utilities (FR 2009a) and cogenerators (FR 2009b)
Annual reporting hours: 3,384
Estimated average hours per response: 1.0 (FR 2009a), 0.5 (FR 2009b)
Number of respondents: 183 (FR 2009a), 198 (FR 2009b)

Small businesses are not affected.

General description of reports: This information collection is voluntary (12 U.S.C. 225a, 263, 353 et seq., and 461)

and is given confidential treatment under the Freedom of Information Act (5 U.S.C. 552(b)(4)).

Abstract: These surveys have collected information on the volume of electric power sold during the month to classes of industrial customers. The electric power data are used in deriving the Federal Reserve's monthly index of industrial production (IP) as well as for calculating the monthly estimates of electric power used by industry. The electric utility industry is currently restructuring in response to deregulation at the federal and state levels. The Federal Reserve revised the FR 2009a such that respondents will report the amount of power *delivered* to industrial customers, instead of power *sold*, so that utilities will continue to report all power consumed by industrial customers connected to their facilities. The FR 2009b was not revised.

Final approval under OMB delegated authority of the extension for three years, without revision, of the following report:

4. *Report title:* Quarterly Gasoline Company Report

Agency form number: FR 2580
OMB Control number: 7100-0009
Frequency: Quarterly

Reporters: Gasoline companies

Annual reporting hours: 4
Estimated average hours per response: 0.15

Number of respondents: 7

Small businesses are not affected.

General description of report: This information collection is voluntary (12 U.S.C. 225a, 263, 353 et seq. and 461) and is given confidential treatment under the Freedom of Information Act (5 U.S.C. 552(b)(4)).

Abstract: The FR 2580 collects information on open-end retail credit outstanding from seven gasoline companies. The information, together with information obtained from other Federal Reserve reports and from secondary sources, is used to construct information on consumer credit for current analysis for monetary policy purposes.

Board of Governors of the Federal Reserve System, August 11, 1997.

William W. Wiles,

Secretary of the Board.

[FR Doc. 97-21651 Filed 8-14-97; 8:45AM]

Billing Code 6210-01-F

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Submission to OMB Under Delegated Authority

Background

Notice is hereby given of the final approval of proposed information collections by the Board of Governors of the Federal Reserve System (Board) under OMB delegated authority, as per 5 CFR 1320.16 (OMB Regulations on Controlling Paperwork Burdens on the Public). The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

FOR FURTHER INFORMATION CONTACT:

Chief, Financial Reports Section—Mary M. McLaughlin—Division of Research and Statistics, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202-452-3829).

OMB Desk Officer—Alexander T. Hunt—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, DC 20503 (202-395-7860).

Final approval under OMB delegated authority of the extension for three years, with revision, of the following reports:

1. *Report titles:* Report of Transaction Accounts, Other Deposits and Vault Cash; Reports of Certain Eurocurrency Transactions; and Advance Reports of Deposits.

Agency form numbers: FR 2900, FR 2950, FR 2951, FR 2000, and FR 2001.

OMB Control number: 7100-0087.

Effective Date: Reporting week ending September 15, 1997, for FR 2900 weekly respondents; reporting week ending September 22, 1997, for FR 2900 quarterly respondents.

Frequency: Weekly, quarterly, daily—dependent upon request.

Reporters: Depository institutions.

Annual reporting hours: 1,281,447.

Report	Estimated average hours per response	Number of respondents
FR 2900	3.50	6,026 weekly; 5,982 quarterly.
FR 2950/2951	1.00	642 weekly; 1 quarterly.
FR 2000	0.84	186.
FR 2001	0.96	540.

Small businesses are affected.

General description of report: This information collection is mandatory (12 U.S.C. 248(a), 461, 603, 615, and 3105(b)(2)) and is given confidential treatment under the Freedom of Information Act (5 U.S.C. 552(b)(4)).

Abstract: This package of reports collects information on: deposits and related items from depository institutions that have transaction accounts or nonpersonal time deposits and that are not fully exempt from reserve requirements ("nonexempt institutions") (FR 2900); Eurocurrency transactions from depository institutions that obtain funds from foreign (non-U.S.) sources or that maintain foreign branches (FR 2950, FR 2951); and selected items on the FR 2900 in advance from samples of nonexempt institutions on a daily basis (FR 2000) and on a weekly basis (FR 2001). The Federal Reserve has raised the deposit cutoff used to determine weekly versus quarterly FR 2900 reporting (the "nonexempt deposit cutoff") above its indexed level of \$59.3 million to \$75.0 million. The higher cutoff will result in a potential shift of almost 1,000 reporters from weekly to quarterly FR 2900 reporting and a significant reduction in annual reporting burden. No revisions to the content of any of the reports have been made. Information provided by these reports is used for administering Regulation D—Reserve Requirements of Depository Institutions; or for constructing, analyzing, and controlling the monetary and reserves aggregates; or both.

Final approval under OMB delegated authority of the extension for three years, without revision, of the following reports:

1. **Report titles:** Quarterly Report of Selected Deposits, Vault Cash and Reservable Liabilities; Annual Report of Total Deposits and Reservable Liabilities.

Agency form numbers: FR 2910q, FR 2910a.

OMB Control number: 7100-0175.

Frequency: Quarterly, annually.

Reporters: Depository institutions.

Annual reporting hours: 3,896 (FR 2910q), 2,838 (FR 2910a).

Estimated average hours per response: 2.0 (FR 2910q), 0.5 (FR 2910a).

Number of respondents: 487 (FR 2910q), 5,675 (FR 2910a) Small businesses are affected.

General description of report: This information collection is mandatory (12 U.S.C. 248(a) and 461) and is given confidential treatment under the

Freedom of Information Act (5 U.S.C. 552(b)(4)).

Abstract: These reports collect information from depository institutions (other than U.S. branches and agencies of foreign banks and Edge and agreement corporations) that are fully exempt from reserve requirements under the Garn-St Germain Depository Institutions Act of 1982. Information provided by these reports is used to construct and analyze the monetary aggregates and to ensure compliance with Regulation D—Reserve Requirements of Depository Institutions.

2. **Report title:** Allocation of Low Reserve Tranche and Reservable Liabilities Exemption.

Agency form number: FR 2930, FR 2930a.

OMB Control number: 7100-0088.

Frequency: Annually, and on occasion.

Reporters: Depository institutions.

Annual reporting hours: 86.

Estimated average hours per response: 0.25

Number of respondents: 342.

Small businesses are affected.

General description of reports: This information collection is mandatory (FR 2930: 12 U.S.C. 248(a), 461, 603, and 615; FR 2930a: 12 U.S.C. 248(a) and 461) and is given confidential treatment under the Freedom of Information Act (5 U.S.C. 552(b)(4)).

Abstract: The FR 2930 and the FR 2930a provide information on the allocation of the low reserve tranche and reservable liabilities exemption for depository institutions having offices (or groups of offices) that submit separate FR 2900 deposits reports. The data collected on these reports are needed for the calculation of required reserves.

Board of Governors of the Federal Reserve System, August 11, 1997.

William W. Wiles,

Secretary of the Board.

[FR Doc. 97-21653 Filed 8-14-97; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

Expert Panel Workshop

The Agency for Toxic Substances and Disease Registry announces the following workshop.

Name: Expert Panel Workshop on the Feasibility of Measuring Stress Related to Exposure to Hazardous Waste.

Times and Dates: 7:30 a.m.–6:15 p.m., September 10, 1997. 8 a.m.–12 noon, September 11, 1997.

Place: The D. Abbott Turner Center at Emory University, 1703 Clifton Road, NE, Atlanta, Georgia 30329, telephone 404/712-6725.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 175 people.

Purpose: The Agency for Toxic Substances and Disease Registry (ATSDR) is considering the feasibility of measuring stress related to exposure to hazardous waste sites and releases. The purpose of the expert panel workshop is to provide a forum for ATSDR to solicit individual expert consultation on issues of science and public health practice regarding the best means to assess levels of psychosocial stress in communities affected by hazardous waste sites and releases. The workshop will also provide a forum for scientists, public health officials, and community members to discuss the ethical and social issues associated with measuring stress at hazardous waste sites and the implications for public health policy.

Matters To Be Considered: Expert panel members will be assigned into two work groups: (1) Stress Measurement Panel and (2) Community and Public Health Panel. The two groups will meet concurrently during the workshop. The following tasks will be suggested: (1) examine current research approaches and assessment tools for the measurement of psychosocial stress at hazardous waste sites and identify the most effective methods for assessing psychosocial stress at these sites and (2) discuss the social and ethical issues of measuring stress in communities affected by hazardous waste and the implications for public health policy.

Agenda items are subject to change as priorities dictate.

Contact Person For More Information: Deborah L. White, Ph.D., Health Education Specialist, ATSDR, 1600 Clifton Road, NE, M/S E-33, Atlanta, Georgia 30333, telephone 404/639-6218, fax 404/639-6207, email: DGW8@cdc.gov.

Dated: August 8, 1997.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97-21678 Filed 8-14-97; 8:45 am]

BILLING CODE 4163-70-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Administration for Children and Families****Proposed Information Collection Activity; Comment Request****Proposed Projects**

Title: Statewide Automated Child Welfare Information System (SACWIS) Assessment Review Guide.

OMB No.: 0970-0159.

Description: HHS cannot fulfill its obligation to effectively serve the nation's Adoption and Foster Care populations, nor report meaningful and reliable information to Congress (Adoption and Foster Care Analysis and

Reporting System (AFCARS) required by section 479(b)(2) of the Social Security Act, or CAPTA reporting requirements) about the extent of the problems facing these children or the effectiveness of various methodologies designed to provide assistance to this population, without access to timely and accurate information. Forty-six States and the District of Columbia have developed or have committed to develop a SACWIS system with enhanced (75 percent) Federal financial participation (FFP). The purpose of these reviews is to ensure that all aspects of the project, as described in the approved Advance Planning Document (APD), have been adequately completed, and confirm with applicable regulations and policies.

States will submit the completed SACWIS Assessment Review Questionnaire and other documentation. The additional documents should all be readily available to the State as a result of good project management.

The information collected in the Assessment Review Guide will allow State and Federal officials to determine if the State's SACWIS system meets the requirements for enhanced title IV-E Federal financial participation defined at 45 CFR 1355.50. Additionally, other States will be able to use the documentation provided as part of this review process, in their own system development efforts.

Respondents: State, Local or Tribal Govt.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Review	15	1	24	360

Estimated Total Annual Burden Hours: 360.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) 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. Consideration will be given to

comments and suggestions submitted within 60 days of this publication.

Dated: August 11, 1997.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 97-21592 Filed 8-14-97; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****Advisory Committee; Notice of Meeting**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Science Board to the Food and Drug Administration.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on September 30, 1997, 8:30 a.m. to 4:30 p.m.

Location: Washington Plaza Hotel, Washington room, 10 Thomas Circle NW., Washington, DC.

Contact Person: Susan K. Meadows, Office of Science (HF-32), Food and

Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4591, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12603. Please call the Information Line for up-to-date information on this meeting.

Agenda: Information will be presented to the board regarding the Biomaterials Forum (a process for information exchange addressing issues in biomaterials science), the FDA Information Retrieval System (FIRSt), the activities of the Science Board Subcommittee on Toxicology, and current status of FDA's implementation of the recommendations of the board's Subcommittee on FDA Research. General discussion will follow on the agency's research and science program plans, peer review programs, and collaborative scientific efforts.

Procedure: On September 30, 1997, from 9:30 a.m. to 4:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 1, 1997. Oral presentations from the public will be scheduled between approximately 3 p.m. and 4 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 1, 1997, and

submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On September 30, 1997, from 8:30 a.m. to 9:30 a.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The board will discuss nominations for, and select recipients of, the 1997 FDA Scientific Achievement Awards. Such discussion in a public meeting would disclose information of a personal nature and would constitute a clearly unwarranted invasion of personal privacy.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 7, 1997.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 97-21722 Filed 8-14-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-437]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. Type of Information Collection Request: Extension of a currently approved collection; **Title of Information Collection:** Psychiatric Unit

Criteria Work Sheet, Rehabilitation Unit Criteria Work Sheet, Rehabilitation Hospital Criteria Work Sheet and Supporting Regulations 42 CFR 412.20-412.32; **Form No.:** HCFA-437; **Use:** Rehabilitation hospitals and Psychiatric hospital units that are excluded from the Medicare Prospective Payment System (PPS) must complete the criteria work sheets to verify and reverify that they comply and remain in compliance with the exclusion criteria for the Medicare prospective payment system. These forms capture information that will allow Medicare to reimburse these facilities on the basis of nationally-determined average standardized amounts, i.e., a prospective payment type system. **Frequency:** Annually; **Affected Public:** Business or other for-profit, Not-for-profit institutions and State, Local or Tribal Government; **Number of Respondents:** 2,555; **Total Annual Responses:** 2,555; **Total Annual Hours:** 639.

2. Type of Information Collection Request: Revision of a currently approved collection; **Title of Information Collection:** Reconciliation of State Invoice and Prior Quarter Adjustment Statement; **Form No.:** HCFA-304A; **Use:** In response to a need for improved data exchange between drug labelers and States, HCFA, in conjunction with outside consultants, developed the Reconciliation of State Invoice (ROSI), form HCFA-304, and the Prior Quarter Adjustment Statement (PQAS), form HCFA-304A. The ROSI is to be used by drug labelers when responding to State invoices of current quarter utilization data only, and functions as a reconciliation report to assure accurate drug rebate payments. The PQAS is used by drug labelers to report only on prior quarter actions/payments. Prior quarter activity includes changes to utilization data submitted by States, revisions to previously disputed units, and prior period adjustments (URA changes). Both forms assist in reducing disputes by standardizing data exchange and improving communication between drug labelers and States. **Frequency:** Quarterly; **Affected Public:** Business or other for-profit; **Number of Respondents:** 365; **Total Annual Responses:** 1,460; **Total Annual Hours:** 132,120.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and

recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address:

HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: John Rudolph, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: August 5, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards, Health Care Financing Administration.

[FR Doc. 97-21654 Filed 8-14-97; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-2384]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Reinstatement, without change, of a previously approved collection for which approval has expired; **Title of Information Collection:** Third Party Premium Billing Request and Supporting Regulations in 42 CFR 408.6; **Form No.:** HCFA-2384 (OMB 0938-0041); **Use:** The Third Party Premium Billing Request is used as an authorization form to designate that a family member or other interested party

receive the Medicare premium bill and pay it on behalf of a Medicare beneficiary. *Frequency:* On occasion; *Affected Public:* Individuals or Households; *Number of Respondents:* 15,000; *Total Annual Responses:* 15,000; *Total Annual Hours:* 6,250.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: August 5, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards, Health Care Financing Administration.

[FR Doc. 97-21650 Filed 8-14-97; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Initial Review Group (IRG) meeting:

Name of IRG: Clinical Trials Review Committee.

Date: October 26-29, 1997.

Time: 7:00 p.m.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, Maryland 20814.

Contact Person: Dr. Joyce A. Hunter, 6701 Rockledge Drive, Rm. 7192, MSC 7924, Bethesda, Maryland 20892, (301) 435-0287.

Purpose/Agenda: To review and evaluate grant applications.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Programs Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health)

Dated: August 8, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97-21624 Filed 8-14-97; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Heart, Lung, and Blood Special Emphasis Panel (SEP) meeting:

Name of SEP: Jackson Heart Study Feasibility Study (Telephone Conference Call).

Date: September 3, 1997.

Time: 2:00 p.m.

Place: Two Rockledge Center, 6701 Rockledge Drive, Room 7214, Bethesda, Maryland 20892.

Contact Person: C. James Scheirer, Ph.D., Two Rockledge Center, Room 7214, 6701 Rockledge Drive, Bethesda, MD 20892-7924, (301) 435-0266.

Purpose/Agenda: To review and evaluate contract proposals.

This meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than fifteen days prior to this meeting due to the urgent need to meet timing limitations imposed by the grant/contract review and funding cycle.

(Catalog of Federal Domestic Assistance Programs Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health)

Dated: August 8, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97-21625 Filed 8-14-97; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental Research; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice

is hereby given of the following National Institute of Dental Research Special Emphasis Panel (SEP) meeting:

Name of SEP: National Institute of Dental Research Special Emphasis Panel—Review of R01 (97-62).

Dates: September 4, 1997.

Time: 3:00 p.m.

Place: Natcher Building, Rm. 4AN-44F, National Institutes of Health, Bethesda, MD 20892 (teleconference).

Contact Person: Dr. George Hausch, Chief, Grants Review Section, 4500 Center Drive, Natcher Building, Room 4AN-44F, Bethesda, MD 20892, (301) 594-2372.

Purpose/Agenda: To evaluate and review grant applications and/or contract proposals.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research)

Dated: August 11, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97-21616 Filed 8-14-97; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council and Its Subcommittees

Pursuant to Pub. L. 92-463, notice is hereby given of a meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council and its subcommittees, National Institute of Diabetes and Digestive and Kidney Diseases, on September 17-18, 1997. The meeting of the full Council will be open to the public on September 17, from 8:30 a.m. to 12:00 p.m. in Conference Room 6, Building 31C, National Institutes of Health, Bethesda, Maryland, to discuss administrative issues relating to Council business and

special reports. The following subcommittee meetings will be open to the public on September 17 from 1:00 p.m. to 2:00 p.m.: Diabetes, Endocrine and Metabolic Diseases Subcommittee meeting will be held in Conference Room 6, Building 31C; Digestive Diseases and Nutrition Subcommittee meeting will be held in Conference Room 7, Building 31C; and Kidney, Urologic and Hematologic Diseases Subcommittee meeting will be held in Conference Room 8, Building 31C. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Pub. L. 92-463, the meetings of the subcommittees and full Council will be closed to the public for the review, discussion and evaluation of individual grant applications. The following subcommittees will be closed to the public on September 17, from 2:00 p.m. to 5:00 p.m.: Diabetes, Endocrine and Metabolic Diseases Subcommittee; Digestive Diseases and Nutrition Subcommittee; and Kidney, Urologic and Hematologic Diseases Subcommittee. The full Council will meet in closed session on September 18 from 8:30 a.m. to 10:00 a.m. in Conference Room 6, Building 31C. These deliberations, whether held in a subcommittee or in the full council, could reveal confidential trade secrets or commercial property, such as patentable materials, and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

A final open session of the full Council will be held on September 18th from 10:00 a.m. to 12:00 p.m. to hear reports from the Division Directors.

For any further information, and for individuals who plan to attend and need special assistance such as sign language interpretation or other reasonable accommodations, please contact Dr. Walter Stolz, Executive Secretary, National Diabetes and Digestive and Kidney Diseases Advisory Council, NIDDK, Natcher Building, Room 6AS-25C, Bethesda, Maryland 20892, (301) 594-8834, in advance of the meeting.

In addition, upon request, a summary of the meeting and roster of the members may be obtained from the Committee Management Office, NIDDK, Building 45, Room 6AS-37J, National Institutes of Health, Bethesda, Maryland 20892, (301) 594-8892.

(Catalog of Federal Domestic Assistance Program No. 93.847-849, Diabetes, Endocrine and Metabolic Diseases; Digestive Diseases and Nutrition; and Kidney Diseases, Urology and Hematology Research, National Institutes of Health)

Dated: August 11, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97-21618 Filed 8-14-97; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Meetings: National Advisory Allergy and Infectious Diseases Council; Acquired Immunodeficiency Syndrome Subcommittee; Allergy and Immunology Subcommittee; Microbiology and Infectious Diseases Subcommittee

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the National Advisory Allergy and Infectious Diseases Council, National Institute of Allergy and Infectious Diseases, and its subcommittees on September 8-9, 1997. Meetings of the Council, NAAIDC Allergy and Immunology Subcommittee, NAAIDC Microbiology and Infectious Diseases Subcommittee and the NAAIDC Acquired Immunodeficiency Syndrome Subcommittee will be held at the National Institutes of Health, Bethesda, Maryland.

The meeting of the full Council will be open to the public on September 8 in Building 31C, Conference Room 6, from 1 p.m. to approximately 3:30 p.m. for general discussion and program presentations.

On September 9 the meetings of the NAAIDC Allergy and Immunology Subcommittee and NAAIDC Microbiology and Infectious Diseases Subcommittee will be open to the public from 8:30 a.m. until adjournment. The subcommittees will meet in Building 31C, conference rooms 8 and 6 respectively.

The meeting of the NAAIDC Acquired Immunodeficiency Syndrome Subcommittee will be open to the public from 8:30 a.m. until adjournment, on September 9. The subcommittee will meet in the Natcher Building, Conference Room EI.

In accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Pub. L. 92-463, the meeting of the NAAIDC Acquired Immunodeficiency Syndrome

Subcommittee, NAAIDC Allergy and Immunology Subcommittee and the NAAIDC Microbiology and Infectious Diseases Subcommittee will be closed to the public for approximately four hours for review, evaluation, and discussion of individual grant applications. It is anticipated that this will occur from 8:30 a.m. until approximately 1 p.m. on September 8, in conference rooms 7, 8, and 6 respectively. The meeting of the full Council will be closed from 3:30 p.m. until recess on September 8 for the review, discussion, and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Claudia Goad, Committee Management Officer, National Institute of Allergy and Infectious Diseases, Solar Building, Room 3C26, National Institutes of Health, Bethesda, Maryland 20892, 301-496-7601, will provide a summary of the meeting and a roster of committee members upon request. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Goad in advance of the meeting.

Dr. Lawrence Deyton, Acting Director, Division of Extramural Activities, NIAID, NIH, Solar Building, Room 3C20, 6003 Executive Boulevard, Rockville, Maryland 20892, telephone 301-496-7291, will provide substantive program information.

(Catalog of Federal Domestic Assistance Program Nos. 93.855 Immunology, Allergic and Immunologic Diseases Research, 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health)

Dated: August 11, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97-21619 Filed 8-14-97; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice

is hereby given of the following meeting:

Purpose/Agenda: To review a concept statement for a proposed request for contract proposal (RFP).

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel.

Date of Meeting: August 26, 1997 (Telephone Conference).

Time: 1:00 p.m.

Place of Meeting: Willco Building, 6000 Executive Boulevard, Suite 514, Rockville, MD 20892-7003.

Contact Person: Barbara Smothers, 6000 Executive Boulevard, Suite 514, Rockville, MD 20892-7003, 301-443-4821.

The meeting will be closed in accordance with the provisions set forth in sec. 552b(c)(9)(B), Title 5 U.S.C. The discussions could reveal the specific details of future requests for contract proposals (RFPs), the disclosure of which would significantly frustrate implementation of the agency's proposed contract activities.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance, Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; National Institutes of Health)

Dated: August 11, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97-21620 Filed 8-14-97; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting:

Purpose/Agenda: To review and evaluate a request for proposal (RFP).

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel.

Date of Meeting: August 26, 1997 (Telephone Conference).

Time: 2:00 p.m.

Place of Meeting: Willco Building, 6000 Executive Boulevard, Suite 514, Rockville, MD 20892-7003.

Contact Person: Barbara Smothers, 6000 Executive Boulevard, Suite 514, Rockville, MD 20892-7003, 301-443-4821.

The meeting will be closed in accordance with the provisions set forth in secs.

552b(c)(4) and 552b(c)(6), Title 5 U.S.C. The proposal and discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the proposal, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance, Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; National Institutes of Health)

Dated: August 11, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97-21623 Filed 8-14-97; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Division of Research Grants; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Division of Research Grants Special Emphasis Panel (SEP) meetings:

Purpose/Agenda: To review individual grant applications.

Name of SEP: Microbiological and Immunological Sciences.

Date: August 18, 1997.

Time: 1:00 p.m.

Place: NIH, Rockledge 2, Room 4178, Telephone Conference.

Contact Person: Dr. Jean Hickman, Scientific Review Administrator, 6701 Rockledge Drive, Room 4178, Bethesda, Maryland 20892, (301) 435-1146.

This notice is being published less than 15 days prior to the above meeting due to the urgent need to meet timing limitations imposed by the grant review and funding cycle.

Name of SEP: Biological and Physiological Sciences.

Date: August 26, 1997.

Time: 2:00 p.m.

Place: NIH, Rockledge 2, Room 4150, Telephone Conference.

Contact Person: Dr. Marcia Litwack, Scientific Review Administrator, 6701 Rockledge Drive, Room 4150, Bethesda, Maryland 20892, (301) 435-1719.

Name of SEP: Biological and Physiological Sciences.

Date: September 5, 1997.

Time: 4:00 p.m.

Place: NIH, Rockledge 2, Room 4148, Telephone Conference.

Contact Person: Dr. Philip Perkins, Scientific Review Administrator, 6701 Rockledge Drive, Room 4148, Bethesda, Maryland 20892, (301) 435-1718.

Name of SEP: Behavioral and Neurosciences.

Date: September 8, 1997.

Time: 9:00 a.m.

Place: Bethesda Hyatt Regency, Bethesda, MD.

Contact Person: Dr. Joseph Kimm, Scientific Review Administrator, 6701 Rockledge Drive, Room 5178, Bethesda, Maryland 20892, (301) 435-1249.

Name of SEP: Biological and Physiological Sciences.

Date: September 15, 1997.

Time: 8:00 a.m.

Place: Holiday Inn-Georgetown, Washington, DC.

Contact Person: Dr. Harish Chopra, Scientific Review Administrator, 6701 Rockledge Drive, Room 5112, Bethesda, Maryland 20892, (301) 435-1169.

The meetings will be closed in accordance with the provisions set forth in secs.

552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 11, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97-21617 Filed 8-14-97; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4235-N-16]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

EFFECTIVE DATE: August 15, 1997.

FOR FURTHER INFORMATION CONTACT: Mark Johnston, Department of Housing and Urban Development, Room 7256, 451 Seventh Street SW, Washington, DC 20410; telephone (202) 708-1226; TDD number for the hearing- and speech-

impaired (202) 708-2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1-800-927-7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless v. Veterans Administration*, No. 88-2503-OG (D.D.C.), HUD publishes a notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: August 7, 1997.

Fred Karnas, Jr.,

Deputy Assistant Secretary for Economic Development.

[FR Doc. 97-21301 Filed 8-14-97; 8:45 am]

BILLING CODE 4210-29-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4248-N-03]

Fiscal Year 1997 Portfolio Reengineering Demonstration Program Request for Qualifications; Announcement of Date for Submission of Qualifications

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

ACTION: Notice of Request for Qualifications; Announcement of Date for Submission of Qualifications.

SUMMARY: On July 16, 1997, the Department published a notice seeking requests for qualifications (RFQ) under a statutory Demonstration Program. The July 16, 1997 RFQ advised that the Department is carrying out a statutory Demonstration Program that is intended to test approaches that reduce the cost of the ongoing Federal subsidy for FHA-insured, Section 8-assisted housing, while preserving this critical affordable housing resource in good physical and financial condition. The July 16, 1997 RFQ is directed to nonprofit organizations that are interested in participating in the Designee process under section VII. of the Guidelines for the Demonstration Program. The Guidelines for the Demonstration Program were published on January 23, 1997.

The July 16, 1997 notice requested that the qualifications be submitted to the Department by August 13, 1997. On

August 13, 1997, the Department published a **Federal Register** notice extending the due date for submission of qualifications indefinitely. The August 13, 1997 notice provided that the Department would announce through a separate notice the new due date for submission of qualifications. This notice supplements the August 13, 1997 notice by establishing this date. The new due date for submission of qualifications is August 25, 1997.

FOR FURTHER INFORMATION CONTACT:

George C. Dipman, Demonstration Program Coordinator, Office of Multifamily Housing, Department of Housing and Urban Development, 451 Seventh Street, S.W., Washington, DC 20410-4000; Room 6106; Telephone (202) 708-3321. (This is not a toll-free number.) Hearing or speech-impaired individuals may call 1-800-877-8399 (Federal Information Relay Service TTY). Internet address: PRE@hud.gov.

SUPPLEMENTARY INFORMATION: On July 16, 1997 (62 FR 38109), the Department published a notice seeking requests for qualifications (RFQ) under a statutory Demonstration Program. The July 16, 1997 RFQ advised that the Department is carrying out a statutory Demonstration Program that is intended to test approaches that reduce the cost of the ongoing Federal subsidy for FHA-insured, Section 8-assisted housing, while preserving this critical affordable housing resource in good physical and financial condition. The July 16, 1997 RFQ is directed to nonprofit organizations that are interested in participating in the Designee process under section VII. of the Guidelines for the Demonstration Program. The Guidelines for the Demonstration Program were published on January 23, 1997 (62 FR 3567).

The July 16, 1997 notice requested that the qualifications be submitted to the Department by August 13, 1997. On August 13, 1997, the Department published a **Federal Register** notice extending the due date for submission of qualifications indefinitely. The August 13, 1997 notice provided that the Department would announce through a separate notice the new due date for submission of qualifications. This notice supplements the August 13, 1997 notice by establishing this new date.

The new due date for submission of qualifications is August 25, 1997.

No other change is made to the July 16, 1997 notice other than the extension of the submission date for qualifications.

Dated: August 13, 1997.

Nicolas P. Retsinas,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 97-21785 Filed 8-13-97; 11:11 am]

BILLING CODE 4210-27-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Convention on International Trade in Endangered Species (CITES) Notification; Rescinding of Prohibition of Trade in Specimens of *Eunectes Notaeus* From Argentina

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of Information No. 27.

SUMMARY: This Notice of Information (NOI) is an update from the prohibitions identified in NOI 13. Specifically, this NOI removes the prohibition on trade in specimens of *Eunectes notaeus* from Argentina identified in NOI 13, published on April 6, 1987 (52 FR 10955).

DATES: This notice is effective on August 15, 1997 and will be effective until further notice.

ADDRESSES: U.S. Fish and Wildlife Service, Office of Management Authority, Mail Stop 430 ARLSQ, 1849 C Street NW, Washington, DC 20240 regarding Notifications to the Parties, or U.S. Fish and Wildlife Service, Division of Law Enforcement, P.O. Box 3247, Arlington, VA 22203-3247, regarding enforcement actions.

FOR FURTHER INFORMATION CONTACT: Dr. Susan S. Lieberman, U.S. Fish and Wildlife Service, Office of Management Authority, telephone (703) 358-2095, regarding Notifications to the Parties, or Thomas L. Striegler, Chief, U.S. Fish and Wildlife Service, Division of Law Enforcement, telephone (703) 358-1949, for enforcement actions.

SUPPLEMENTARY INFORMATION: On May 7, 1986, the CITES Secretariat issued Notification to the Parties No. 384, which recommended that all Parties assist Argentina in the implementation of Argentina Resolution No. 24/86, which prohibited the export of live specimens, as well as parts and derivatives of *Boa constrictor occidentalis*, *Eunectes notaeus* and *Rhea americana*. Argentina Resolution No. 24/86 contained a provision for the exportation of parts and derivatives of these species provided that such parts and derivatives were registered with the CITES Management Authority of Argentina and that exportation was

completed within a period of 180 days from the date of publication of Resolution No. 24/86, which was February 23, 1986. For various reasons, the stockpiles of *Eunectes notaeus* skins were not exported within the deadline imposed by Resolution No. 24/86. Recognizing this fact, the CITES Management Authority of Argentina consulted with the CITES Animals Committee to determine how to resolve the situation in order to allow the exportation of these stockpiles. The CITES Animals Committee recommended that the CITES Management Authority of Argentina should make an inventory of all legal stocks of *Eunectes notaeus* specimens. The CITES Management Authority of Argentina announced that it has completed this inventory and registration of *Eunectes notaeus* specimens through the issuance of Resolution No. 333/96, and in so doing, has authorized the exportation of these specimens. On June 2, 1997, the CITES Secretariat issued Notification to the Parties No. 977, which recommended to the Parties that the prohibition of trade with Argentina on specimens of *Eunectes notaeus* be lifted.

The subject of this notice is as follows:

A. Subject: Argentina: ban on imports of specimens of *Eunectes notaeus* from Argentina.

Source of Foreign Law Information: Argentina Resolution No. 333/96.

Action by the Fish and Wildlife Service: Since the publication of Notice of Information No. 13 (52 FR 10955), the Government of Argentina has issued Resolution No. 333/96, to effectively implement the recommendations of the CITES Animals Committee regarding the inventory and registration of all legal stocks of specimens of *Eunectes notaeus*.

The Service is satisfied that Argentina has initiated the action necessary to sufficiently implement the recommendations of the CITES Animals Committee. Therefore, shipments of specimens of *Eunectes notaeus* of Argentine origin may now be imported into the United States provided that such shipments are accompanied by valid CITES reexport certificates from the country of reexport and a copy of the CITES export permit issued by the Management Authority of Argentina indicating that the specimens of *Eunectes notaeus* were legally exported from Argentina in accordance with Resolution No. 333/96.

Dated: August 6, 1997.

Donald Barry,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 97-21707 Filed 8-14-97; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Geological Survey

Request for Public Comments on Information Collection To Be Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

A request extending the collection of information listed below will be submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed collection of information and related forms may be obtained by contacting the Bureau's Clearance Officer at the phone number listed below. Comments and suggestions on the requirement should be made within 60 days directly to the Bureau Clearance Officer, U.S. Geological Survey, 208 National Center, Reston, VA 20192.

As required by OMB regulations at 5 CFR 1320.8(d)(1), the U.S. Geological Survey solicits specific public comments regarding the proposed information collection as to:

1. Whether the collection of information is necessary for the proper performance of the functions of the bureau, including whether the information will have practical utility;
2. The accuracy of the bureau's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
3. The utility, quality, and clarity of the information to be collected; and,
4. How to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated electronic, mechanical, or other forms of information technology.

Title: Lime.

OMB approval number: 1028-New.

Abstract: Respondents supply the U.S. Geological Survey with domestic production, values, end-use data, and capacity information on the domestic lime industry. This information will be published as an Annual Report for use by Government agencies, industry, and the general public.

Bureau form number: 6-1221-A.

Frequency: Annual.

Description of respondents: Commercial and captive producers of

quicklime, hydrated lime, and dead-burned dolomite.

Annual Responses: 107.

Annual burden hours: 160.5.

Bureau clearance officer: John E. Cordyack, Jr., 703-648-7313.

John H. DeYoung, Jr.,

Acting Chief Scientist, Minerals Information Team.

[FR Doc. 97-21640 Filed 8-14-97; 8:45 am]

BILLING CODE 4310-31-M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Operation and Maintenance Rate Adjustment: Flathead Indian Irrigation Project, Montana

ACTION: Notice of proposed operation and maintenance rate increase.

SUMMARY: The Bureau of Indian Affairs proposes to change the assessment rates for operating and maintaining the Flathead Indian Irrigation Project for 1998 and subsequent years from the current rate of \$18.45 per acre to \$19.95 per acre, an increase of \$1.50 per acre. The assessment rates are based on a prepared estimate of the cost of normal operation and maintenance of the irrigation project. Normal operation and maintenance means the expenses we incur to provide direct support or benefit to the project's activities for administration, operation, maintenance, and rehabilitation. We must include at least:

(a) Personnel salary and benefits for the project engineer/manager and our employees under his management control;

(b) Materials and supplies;

(c) Major and minor vehicle and equipment repairs;

(d) Equipment, including transportation, fuel, oil, grease, lease and replacement;

(d) Capitalization expenses;

(e) Acquisition expenses; and

(f) Other expenses we determine

necessary to properly perform the activities and functions characteristic of an irrigation project.

FOR FURTHER INFORMATION CONTACT: Area Director, Bureau of Indian Affairs, Portland Area Office, 911 N.E. 11th Avenue, Portland, Oregon 97232-4169, telephone (503) 231-6702.

DATES: Comments must be submitted on or before September 15, 1997.

SUPPLEMENTARY INFORMATION: The authority to issue this document is vested in the Secretary of the Interior by 5 U.S.C. 301 and the Act of August 15, 1914 (38 Stat. 583, 25 U.S.C. 385). The

Secretary has delegated this authority to the Assistant Secretary—Indian Affairs pursuant to part 209 Departmental Manual, Chapter 8. 1A and Memorandum dated January 25, 1994, from Chief of Staff, Department of the Interior, to Assistant Secretaries, and Heads of Bureaus and Offices.

This notice is given in accordance with Section 171.1(e) of part 171, Subchapter H, Chapter 1, of Title 25 of the Code of Federal Regulations, which provides for the fixing and announcing the rates for annual operation and maintenance assessments and related information of the Flathead Irrigation Project for Calendar Year 1998 and subsequent years.

The purpose of this notice is to announce a proposed increase in the Flathead Irrigation Project assessment rates proportionate with actual operation and maintenance costs. The assessment rates for 1998 will amount to an increase of 8.1%.

Payments

The irrigation operation and maintenance assessments become due based on locally established payment requirements, but in no case later than May 30 of each irrigation season. No water shall be delivered to any of these lands until all irrigation charges have been paid.

Interest and Penalty Fees

Interest, penalty, and administrative fees will be assessed, where required by law, on all delinquent operation and maintenance assessment charges as prescribed in the Code of Federal Regulations, Title 4, part 102, Federal Claims Collection Standards; and 42 BIAM Supplement 3, part 3.8 Debt Collection Procedures. Beginning 30 days after the due date interest will be assessed at the rate of the current value of funds to the U.S. Treasury. An administrative fee of \$12.50 will be assessed each time an effort is made to collect a delinquent debt; a penalty charge of 6 percent per year will be charged on delinquent debts over 90 days old and will accrue from the date the debt became delinquent. No water shall be delivered to any farm unit until all irrigation charges have been paid. After 180 days a delinquent debt will be forwarded to the United States Treasury for further action in accordance with Debt Collection Improvement Act of 1996 (Public Law 104-134).

Dated: July 31, 1997.

Ada E. Deer,

Assistant Secretary—Indian Affairs.

[FR Doc. 97-21588 Filed 8-14-97; 8:45 am]

BILLING CODE 4310-02-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV-030-1220-00; Closure Notice No. NV-030-97-005]

Emergency Closure of Federal Lands

SUMMARY: Notice is hereby given that certain public lands west of Red Rock Road, Washoe County, Nevada, are closed to all motorized vehicles. This closure is necessary due to unauthorized road construction and off-road vehicle use which is causing considerable adverse effects to soil, vegetation and wildlife habitat in the area.

DATES: This closure goes into effect on August 15, 1997, and will remain in effect until the Carson City District Manager determines it is no longer needed.

FOR FURTHER INFORMATION CONTACT:

Clifford Ligons, Assistant District Manager, Division on Non-Renewable Resources, Carson City District, 1535 Hot Springs Road, Carson City, Nevada 89706. Telephone (702) 885-6000.

SUPPLEMENTARY INFORMATION: The authorities for this closure are 43 CFR 8341.2, 43 CFR 8342.3 and 43 CFR 8364.1. Any person who fails to comply with a closure order is subject to arrest and fines in accordance with applicable provisions of 18 U.S.C 3571 and/or imprisonment not to exceed 12 months.

This closure applies to all motorized vehicles excluding (1) any emergency or law enforcement vehicle while being used for emergency purposes, and (2) any vehicle whose use is expressly authorized in writing by the Carson City District Manager.

The public lands affected by this closure are located north of Reno, Nevada, approximately one mile southwest of Red Rock Road, and include lands within:

Mt. Diablo Meridian

T.22N., R.18E.

Sec. 11, NE $\frac{1}{4}$ NW $\frac{1}{4}$.

A map of the area closed to motorized vehicles is posted in the Carson City District Office.

Dated: August 1, 1997.

John O. Singlaub,

Carson City District Manager.

[FR Doc. 97-21639 Filed 8-14-97; 8:45 am]

BILLING CODE 4310-HC-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV-033-1230-00-FR97009]

Temporary Closure of Public Lands; Nevada

AGENCY: Bureau of Land Management, Interior Department.

ACTION: Temporary closure of certain public lands, Carson City District, in Lyon, Mineral, Churchill, and Douglas Counties on and adjacent to two Off Highway Vehicle Race courses:

(1) Best in the Desert Racing—Permit Number NV-055-97-35: Las Vegas to Reno Off-highway Vehicle Race occurring September 19-20, 1997.

(2) High Sierra Motorcycle Club—Permit Number NV-030-97043: Silver State Hare 'N' Hound Off-highway Motorcycle Race occurring September 21, 1997.

PURPOSE: To provide for public safety and to protect adjacent resources.

EFFECTIVE DATES: September 19, 20, 21, 1997.

SUPPLEMENTARY INFORMATION: A map of each closure may be obtained at the contact address. The permittees are required to clearly mark and monitor the event routes during each closure period. Spectators shall remain in safe locations as directed by event officials and BLM personnel. The public lands to be closed to public use include existing roads, jeep trails and dry washes identified on the ground by colorful flagging and paper arrows attached to wooden stakes designating the race route. Specific information pertaining to each event follows:

(1) The 'Vegas to Reno Race is a 550 mile point-to-point event beginning early Friday morning, September 19, in Las Vegas. Racing will end on the Old Como Road south of Dayton. Como Road to Rawe Peak will be closed to all public use. Vehicles include motorcycles and fourwheel drive trucks. The closed route crosses public lands within the following areas from 6 a.m. September 19 through noon, September 20, 1997:

Mineral County—R37E, T5N; R36E, T6N; R35E, T6-11N; R34E, T8-13N; R33-32E, T13N. Churchill County—R32E, T14N; R31E, T15N; R30E, T15-16N, R29-24E, T16N; R24E, T15N; R23-21E, T15N; R21E, T16N. Douglas County—R23E, T14N.

(2) The Silver State Hare 'N' Hound is a one-lap, motorcycle race along 60 to 90 miles of dirt roads and dry wash trails located in the Wassuk foothills east of Yerington, Nevada in Lyon and Mineral Counties within T12N R26-

27E; T13N, R26–27E; T14N R27E. This closure will be in effect from 6:00 a.m. through 4:00 p.m. on Sunday, September 21, 1997.

EXCLUSIONS: The above restrictions do not apply to agency, race officials, law enforcement, or emergency response personnel during the conduct of their official duties in relation to the race event.

Authority: 43 CFR 8364 and 43 CFR 8372.

PENALTY: Any person failing to comply with the closure order may be subject to imprisonment for not more than 12 months, or a fine in accordance with the applicable provisions of 18 U.S.C. 3571, or both.

FOR FURTHER INFORMATION CONTACT: Fran Hull, Outdoor Recreation Planner, Carson City District, Bureau of Land Management, 1535 Hot Springs Road, Carson City, Nevada 89706. Telephone: (702) 885–6000.

Dated: August 4, 1997.

Clifford D. Ligons,
Assistant District Manager, Non-Renewable Resources.

[FR Doc. 97–21641 Filed 8–14–97; 8:45 am]

BILLING CODE 4310–HC–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–985–0777–66]

Supplementary Rule Requiring the Use of Certified Noxious Weed-Free Forage on Public Lands in the Bighorn Basin, Wyoming and the Availability of the Environmental Assessment, Decision Record, and Finding of No Significant Impact for Implementation of Requirements for Weed-Free Forage on Public Lands in the Bureau of Land Management's Worland District, Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notices.

SUMMARY: The Worland District of the Bureau of Land Management (BLM) recently prepared an environmental assessment (EA) documenting the analysis of two alternatives for managing noxious weeds on public lands in the Bighorn Basin of Wyoming. The EA's proposed action consisted of a supplementary rule under 43 CFR 8365.1–6 to require the use of certified noxious weed-free forage on those public lands. Forage subject to this rule would include hay, cubes, straw, and mulch. The District Manager of the BLM's Worland District has issued a

decision record that the EA's proposed action and supplemental rule will not have any significant impact on the human environment and that an environmental impact statement is not required. Therefore, the District Manager is requiring that public land users, including permittees and local, state, or federal government agents conducting administrative activities, use certified noxious weed-free forage on BLM-administered public lands in the Worland District, Wyoming. In addition to certified weed-free forage, the use of pelletized feeds and grain products is authorized.

The Worland District encompasses approximately 3,089,600 acres of public land in Big Horn, Hot Springs, Park, and Washakie counties in Northwestern Wyoming. This rule will affect public land users who use hay or other forage products on the BLM-administered public lands in the Worland District such as recreationists using pack and saddle stock, ranchers with grazing permits, outfitters, and contractors who use straw or other mulch for reclamation purposes. These individuals or groups would be required to use only certified noxious weed-free forage products, while on BLM-administered public lands in the Worland District, Wyoming.

EFFECTIVE DATES: The rule will become effective September 1, 1997 and will remain in effect until modified or rescinded by the Authorized Officer.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, Worland District Office, Roger Inman, Resource Advisor, P. O. Box 119, 101 South 23rd Street, Worland, Wyoming 82401–0119, or telephone (307) 347–5292.

SUPPLEMENTARY INFORMATION: The environmental assessment (EA) is consistent with the land-use plans for the Worland District.

Noxious and undesirable weeds are a serious problem in the western United States. Estimates of the rapid spread of weeds in the west include 2,300 acres per day on BLM-administered public lands and 4,600 acres per day on all federally-administered land in the west. Species such as leafy spurge, spotted knapweed, Russian knapweed, musk thistle, dalmatian toadflax, purple loosestrife, houndstongue, and other non-native noxious and undesirable weeds have no natural controls to keep their populations in balance. Consequently, these weeds invade healthy ecosystems, displace native vegetation, reduce species diversity, and damage wildlife habitat. Widespread infestations lead to soil erosion and stream sedimentation. Furthermore,

noxious weed invasions weaken revegetation efforts, reduce livestock and wildlife grazing capacity, occasionally affect the health of public land users by aggravating allergies and other ailments, and threaten federally-protected or native plants and animals.

To help reduce the spread of noxious weeds, a number of Western States have jointly developed noxious weed-free forage certification standards, and, in cooperation with various federal, state, and county agencies, passed weed management laws. Because hay and other forage products containing noxious weed seed are part of the infestation problem, Wyoming has developed a state crop inspection; a certification-identification process; participates in a regional inspection certification-identification process; and encourages forage producers in Wyoming to grow noxious weed-free products and have them certified.

Region II of the United States Forest Service, Department of Agriculture, implemented a similar policy for all National Forest lands in Wyoming in 1996. The Wyoming BLM implemented a standard stipulation on all Special Recreation Permits in 1994, requiring permit holders who use livestock to use certified noxious weed-free products. This proposal will provide a standard regulation for all users of BLM-administered public lands in the Worland District and will provide for coordinated and consistent management with the U.S. Forest Service.

In cooperation with the State of Wyoming and the U.S. Forest Service, the Worland District is implementing a ban of the use of forage that has not been certified, on all BLM-administered lands within the Worland District. This proposal includes public information to insure that: (1) This ban is well publicized and understood, and (2) visitors to and land users of public lands administered by the Worland District BLM will know where they can purchase state-certified hay and other forage products.

These supplementary rules will not appear in the Code of Federal Regulations. The principal author of these supplementary rules is Roger Inman, Resource Advisor, of the Worland District, Wyoming BLM.

For the reasons stated above, under the authority of 43 Code of Federal Regulations 8365.1–6, the Worland District Manager issues supplementary rules to read:

Supplementary Rules to Require the Use of Certified Noxious Weed-Free Forage on Bureau of Land Management-

Administered Public Lands in the Worland District, Wyoming.

1. To help prevent the spread of weeds on BLM-administered lands in Big Horn, Hot Springs, Park, and Washakie counties of Wyoming, effective September 1, 1997, all BLM-administered public lands within the BLM's Worland District of Wyoming, shall be closed to possessing, transporting or storing hay, cubes, straw, and mulch that has not been certified as free of noxious weed seed.

2. Certification will comply with "Regional Weed Free Forage Certification Standards," jointly developed by the states of Wyoming, Idaho, Montana, Colorado, Utah, and Nebraska, for noxious weed-free forage.

3. The following persons are exempt from this order: (1) Any person with a permit signed by an authorized officer of the BLM's Bighorn Basin Resource Area office or the Cody Resource Area office, specifically authorizing the prohibited act or omission within that resource area; (2) Persons possessing or using pelletized feed or grain products; and (3) Persons transporting forage products on Federal and State Highways and County roads.

4. Any person who knowingly and willfully violates the provisions of these supplemental rules may be commanded to appear before a designated United States Magistrate and may be subject to a fine of not more than \$1,000 or imprisonment of not more than 12 months, or both, as defined in 43 United States Code 1733(a).

Dated: July 29, 1997.

Darrell Barnes,

District Manager.

[FR Doc. 97-21628 Filed 8-14-97; 8:45 am]

BILLING CODE 4310-22-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AZ-030-1920-00-4305]

Notice of Intent To Prepare an Environmental Impact Statement for the Proposed Improvement of Diamond Bar Road From the Pearce Ferry Road Near Meadview, Arizona, to the Western Boundary of the Hualapai Indian Reservation in Mohave County, AZ

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent, notice of scoping period, and notice of scoping meetings.

SUMMARY: Pursuant to Section 102(2)(C) of the National Environmental Policy

Act of 1969, the Bureau of Land Management (BLM), Kingman Field Office, will be directing the preparation of an environmental impact statement (EIS) to analyze the impacts of a proposal to improve Diamond Bar Road, an existing unimproved road that crosses BLM and private lands in northwestern Arizona. The project proponent is the Bureau of Indian Affairs (BIA), Truxton Canyon Agency. The Bureau of Indian Affairs proposes to widen the existing road to a two-lane highway, pave it, construct dirt shoulders on each side, and install culverts as needed. Approximately 70 percent of the proposed roadway would follow the alignment of the existing road. This proposal conforms with BLM's Kingman Resource Area Resource Management Plan, approved in 1995. The BLM will act as Lead Agency and the BIA as Cooperating Agency for preparation of the EIS.

This notice is intended to invite the public to participate in identifying issues and developing alternatives for the proposal.

DATES: Three meetings to identify public concerns will be held on the following dates at the locations indicated. Each meeting is scheduled to start at 6-8 p.m. September 3, 1997, Holiday Inn, 3100 East Andy Devine, Kingman, Arizona 86401

September 4, 1997, VFW Hall, 15943 Pearce Ferry Road, Dolan Springs, Arizona 86441

September 5, 1997, Hualapai Multipurpose Building, 921 Hualapai Way, Peach Springs, Arizona 86434

Comments relating to the identification of issues and alternatives will be accepted for up to 30 days following the publication of this notice.

ADDRESSES: Send comments to: Bureau of Land Management, Kingman Field Office, 2475 Beverly Avenue, Kingman, Arizona 86401.

FOR FURTHER INFORMATION, CONTACT: Don McClure, Project Manager, (520) 757-3161.

SUPPLEMENTARY INFORMATION: The purpose of and need for this project are to enhance the safety and efficiency of motorized travel on Diamond Bar Road and to accommodate projected future traffic demand resulting from further development of Grand Canyon West on the Hualapai Indian Reservation. Diamond Bar Road provides access to Grand Canyon West, primarily for commercial and private vehicles originating from Las Vegas. Grand Canyon West is a development near the rim of the Grand Canyon that currently consists of an airport and associated

terminal building, a food service facility, restrooms, and a permits office. Implementation of a master plan for Grand Canyon West completed in 1994, is expected to cause up to a sixfold increase in the total number of visitors over a ten-year period. This increase would result in a substantial increase in the number of vehicles on Diamond Bar Road. The proposed improvement of Diamond Bar Road would accommodate this increased volume by providing a roadway designed for up to 2,400 vehicles per day.

Anticipated Issues

Management concerns that will be addressed include, but are not limited to, impacts on vegetation, visual quality, recreation, cultural resources, socioeconomic, public safety, and the Joshua Tree Forest Area of Critical Environmental Concern. Studies to be conducted include a native plant inventory, biological evaluation, cultural resource survey, traffic study, and visual impact analysis. Tribal consultation pursuant to Section 106 of the National Historic Preservation Act of 1966, as amended, is ongoing.

Other Relevant Information

The EIS will be prepared by an interdisciplinary team of resource specialists in the fields of vegetation (including salvage), wildlife, visual quality, archaeological and traditional cultural resources, soils, range management, realty, and roadway design. Complete records of all phases of the EIS process will be available for public review at the Kingman Field Office, 2475 Beverly Avenue, Kingman, 86401.

Dated: August 11, 1997.

Michael A. Ferguson,

Acting State Director.

[FR Doc. 97-21638 Filed 8-14-97; 8:45 am]

BILLING CODE 4310-32-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV-030-1220-00; Federal Register Notice No. NV-030-97-006]

Limited Use Designation of Federal Lands

SUMMARY: Notice is hereby given that the boundary of the Jumbo-Bailey Watershed Limited Use Area. Washoe County, Nevada, has been expanded. Furthermore, motorized vehicle traffic is restricted to designated routes. The term "designated routes" replaces the

original restriction first published on September 15, 1988, which appeared as "designated maintained roads." This action is taken to carry out the intent of current land use plan decisions to protect soil and watershed values in the Jumbo/Bailey Watershed.

DATES: This Limited Use Designation goes into effect on August 15, 1997.

FOR FURTHER INFORMATION CONTACT: Clifford Ligons, Assistant District Manager, Division on Non-Renewable Resources, Carson City District, 1535 Hot Springs Road, Carson City, Nevada 89707. Telephone (702) 885-6000.

SUPPLEMENTARY INFORMATION: The authorities for this closure are 43 CFR 8341.1, and 43 CFR 8342.1. Any person who fails to comply with a closure order is subject to arrest and fines in accordance with applicable provisions of 18 USC 3571 and/or imprisonment not to exceed 12 months.

This limited use are a designation applies to all motorized vehicles excluding (1) any emergency or law enforcement vehicle while being used for emergency purposes, and (2) any vehicle whose use is expressly authorized in writing by the Assistant District Manager, Division of Non-Renewable Resources.

The public lands affected by this explanation of the Limited Use Area are located in the Jumbo-Bailey Watershed and include lands within:

Mt. Diablo Meridian

T.17N., R.20E.

Secs. 3, 9, 10, 11.

A map of the designated routes open to motorized vehicles is posted in the Carson City District Office.

Dated: August 1, 1997.

John O. Singlaub,

Carson City District Manager.

[FR Doc. 97-21631 Filed 8-14-97; 8:45 am]

BILLING CODE 4310-HC-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CO-010-07-1020-00-241A]

Northwest Colorado Resource Advisory Council Meetings

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of meeting.

SUMMARY: The next meetings of the Northwest Colorado Resource Advisory Council will be held on Tuesday, September 9, 1997, in Grand Junction, Colorado; and Friday, November 7, 1997, in Eagle, Colorado.

DATES: Meetings are scheduled for Tuesday, September 9, 1997, and Friday, November 7, 1997.

ADDRESSES: For further information, contact Joann Graham, Bureau of Land Management (BLM), Grand Junction District Office, 2815 H Road, Grand Junction, Colorado 81506; Telephone (970) 244-3037.

SUPPLEMENTARY INFORMATION: *Tuesday, September 9, 1997.* A business meeting will be held from 6 a.m. to 8 a.m. in the Grand Junction District Office conference room, 2815 H Road, Grand Junction, Colorado. Agenda topics include draft 3809 mining regulations update, sanctioned subcommittee reports, and wilderness review update. The business meeting will be followed by a raft trip down the Colorado River through Ruby Canyon.

Friday, November 7, 1997. This meeting will be held in Eagle, Colorado. The meeting time, location, and agenda will be posted at a later time.

All resource advisory council meetings are open to the public. Interested persons may make oral statements at the meetings or submit written statements following the meetings. Per-person time limits for oral statements may be set to allow all interested persons an opportunity to speak.

Summary minutes of council meetings are maintained in both the Grand Junction and Craig District Offices. They are available for public inspection and reproduction during regular business hours within thirty (30) days following the meeting.

Dated: August 5, 1997.

Richard Arcand,

Grand Junction Associate District Manager.

[FR Doc. 97-21632 Filed 8-14-97; 8:45 am]

BILLING CODE 4310-70-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR-050-1020-00: GP7-0258]

Notice of Meeting of John Day-Snake Resource Advisory Council

AGENCY: Bureau of Land Management, Prineville District.

ACTION: Meeting of John Day-Snake Resource Advisory Council: John Day, Oregon; September 16-17, 1997.

SUMMARY: A field trip and meeting of the John Day-Snake Resource Advisory Council will be held on September 16 and September 17, 1997 in John Day, Oregon. On September 16 the Council will tour the Summit Fire on the

Malheur National Forest and the Nature Conservancy Preserve on the Middle Fork John Day River. On September 17, the Council will hold a business meeting at the Malheur National Forest Office located at 431 Patterson Bridge Road, John Day, Oregon, from 8 a.m. to noon. The field tour will leave the John Day Sunset Inn, 390 West Main Street, at 7:30 a.m. on September 16. The field tour and business meeting are open to the public. However, no public transportation will be provided for the field trip. Public comments will be received by the Council at 10:00 a.m. on September 17. Topics to be discussed include the Interior Columbia Basin Ecosystem Management Project, Standards for Rangeland Health and Guidelines for Livestock Grazing on public lands, current issues, and forest health on Forest Service Lands and BLM lands.

FOR FURTHER INFORMATION CONTACT: James L. Hancock, Bureau of Land Management, Prineville District Office, 3050 NE Third Street, Prineville, Oregon 97754, or call 541-416-6700.

Dated: August 1, 1997.

James L. Hancock,

District Manager.

[FR Doc. 97-21633 Filed 8-14-97; 8:45 am]

BILLING CODE 4310-33-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY-985-0777-66]

Emergency Closure for All Motorized Vehicles on BLM-Administered Public Land Along the Rome Hill Stock Drive in T.47 N, R. 88 W., Sections 23, 24, 25 and 26 and T.47 N., R. 87 W., Section 19., Bighorn Basin Resource Area, Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Closure.

SUMMARY: Notice is hereby given that effective immediately, all public lands administered by the Bureau of Land Management (BLM), Worland District in T.47 N, R. 88 W., sections 23, 24, 25 and 26 and T.47 N., R. 87 W., section 19 are closed to all motorized vehicle use. The Worland District BLM has determined that immediate action is needed to stop the spread of spotted knapweed.

EFFECTIVE DATES: This emergency closure is effective immediately and will remain in effect until rescinded or modified by the authorized officer.

FOR FURTHER INFORMATION CONTACT: Chuck Wilkie, Area Manager, Bighorn

Basin Resource Area, P.O. Box 119, 101 South 23rd Street, 82401-0119. Telephone (307) 347-5100.

SUPPLEMENTARY INFORMATION: This closure is in response to a request from the Washakie County Weed and Pest District to control the spread of spotted knapweed, a designated noxious weed. Spotted knapweed is highly competitive and readily establishes on any disturbed soil. Once established, knapweed releases chemical substances which inhibit growth of surrounding vegetation. Knapweed is easily caught up in the undercarriage of motorized vehicles, allowing seed to be spread for miles.

This emergency closure applies to approximately 1,520 acres of public lands along the Rome Hill Stock Drive in T. 47 N., R. 88 W., sections 23, 24, 25 and 26 and T. 47 N., R. 87 W., section 19, Sixth Principal Meridian, Washakie County, Wyoming. Off-road use designations apply to all motorized vehicles with the exceptions of: (1) Any fire, military, emergency, or law enforcement vehicle when used for emergency purposes or any combat support vehicle when used for national defense purposes; (2) Any vehicle whose use is expressly authorized by the Bureau of Land Management under permit, license, or contract; and (3) Any government vehicle on business.

Authority for closure order is provided under 43 CFR subpart 8341.2 (a and b), 8364.1, 8372.0-7, 8372.1-2. Violations of this closure are punishable by a fine not to exceed \$1,000 and (or) imprisonment not to exceed 12 months.

Dated: July 31, 1997.

David Atkins,

Acting Area Manager.

[FR Doc. 97-21629 Filed 8-14-97; 8:45 am]

BILLING CODE 4310-22-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV-065-5700-10; NVN-57452]

Notice of Realty Action: Recreation and Public Purposes (R&PP) Act Classification, Nevada

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The following described public lands in Tonopah, Nye County, Nevada, have been examined and found suitable for conveyance (patent) to Nye County under the provisions of the Recreation and Public Purposes Act of June 14, 1926, as amended (43 U.S.C.

869 *et seq.*). Nye County proposes to use the lands for a municipal solid waste disposal site to serve Tonopah, Nevada, and the surrounding area.

Mount Diablo Meridian, Nevada

T. 2 N., R. 43 E.,

Sec. 4, SW $\frac{1}{4}$ NE $\frac{1}{4}$, W $\frac{1}{2}$ SE $\frac{1}{4}$ NE $\frac{1}{4}$, SW $\frac{1}{4}$ NE $\frac{1}{4}$ NW $\frac{1}{4}$, SW $\frac{1}{4}$ SE $\frac{1}{4}$ NE $\frac{1}{4}$ NW $\frac{1}{4}$, N $\frac{1}{2}$ NE $\frac{1}{4}$ SE $\frac{1}{4}$ NW $\frac{1}{4}$, and NE $\frac{1}{4}$ NW $\frac{1}{4}$ SE $\frac{1}{4}$ NW $\frac{1}{4}$;

Containing 80 acres, more or less.

The lands are not needed for Federal purposes. The conveyance is consistent with current Bureau land use planning for this area and would be in the public interest. The patent, when issued, will be subject to the provisions of the Recreation and Public Purposes Act and applicable regulations of the Secretary of the Interior, and will contain the following reservations to the United States:

1. A right-of-way thereon for ditches and canals constructed by the authority of the United States pursuant to the Act of August 30, 1890 (43 U.S.C. 945);

2. All mineral deposits shall be reserved to the United States, together with the right to prospect for, mine, and remove such deposits from the same under applicable laws and such regulations as the Secretary of the Interior may prescribe,

will contain the following provisions:

1. Nye County, its successors or assigns, assumes all liability for and shall defend, indemnify, and save harmless the United States and its officers, agents, representatives, and employees (hereinafter referred to in this clause as the United States), from all claims, loss, damage, actions, causes of action, expense, and liability (hereinafter referred to in this clause as claims) resulting from, brought for, or on account of, any personal injury, threat of personal injury, or property damage received or sustained by any person or persons (including the patentee's employees) or property growing out of, occurring, or attributable directly or indirectly, to the disposal of solid waste on, or the release of hazardous substances from Mount Diablo Meridian, Nevada, T. 2 N., R. 43 E., sec. 4, SW $\frac{1}{4}$ NE $\frac{1}{4}$, W $\frac{1}{2}$ SE $\frac{1}{4}$ NE $\frac{1}{4}$, SW $\frac{1}{4}$ NE $\frac{1}{4}$ NW $\frac{1}{4}$, SW $\frac{1}{4}$ SE $\frac{1}{4}$ NE $\frac{1}{4}$ NW $\frac{1}{4}$, N $\frac{1}{2}$ NE $\frac{1}{4}$ SE $\frac{1}{4}$ NW $\frac{1}{4}$, and NE $\frac{1}{4}$ NW $\frac{1}{4}$ SE $\frac{1}{4}$ NW $\frac{1}{4}$, regardless of whether such claims shall be attributable to: (1) The concurrent, contributory, or partial fault, failure, or negligence of the United States, or (2) the sole fault, failure, or negligence of the United States;

2. Provided, that the title shall revert to the United States upon a finding,

after notice and opportunity for a hearing, that the patentee has not substantially developed the land in accordance with the approved plan of development on or before the date five years after the date of conveyance. No portion of the land shall under any circumstances revert to the United States if any such portion has been used for solid waste disposal or for any other purpose which may result in the disposal, placement, or release of any hazardous substance;

3. If, at any time, the patentee transfers to another party ownership of any portion of the land not used for the purpose specified in the application and approved plan of development, the patentee shall pay the Bureau of Land Management the fair market value, as determined by the authorized officer, of the transferred portion as of the date of transfer, including the value of any improvements thereon;

4. The above described land has been conveyed for utilization as a solid waste disposal site by Nye County, Nevada. Upon closure, the site may contain small quantities of commercial and household hazardous waste as determined in the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6901), and defined in 40 CFR 261.4 and 261.5. Although there is no indication these materials pose any significant risk to human health or the environment, future land uses should be limited to those which do not penetrate the liner or final cover of the landfill unless excavation is conducted subject to applicable State and Federal requirements; and will be subject to valid existing rights.

Detailed information concerning this action is available for review at the office of the Bureau of Land Management, Tonopah Field Station, 102 Military Circle, Tonopah, Nevada.

Upon publication of this notice in the **Federal Register**, the above described land will be segregated from all other forms of appropriation under the public land laws, including the general mining laws, except for conveyance under the Recreation and Public Purposes Act and leasing under the mineral leasing laws. For a period of 45 days from the date of publication of this notice in the **Federal Register**, interested parties may submit comments regarding the proposed conveyance or land classification to the Field Station Manager, Tonopah Field Station, P.O. Box 911, Tonopah, Nevada 89049.

Classification Comments

Interested parties may submit comments involving the suitability of

the land for a municipal solid waste disposal site. Comments on the classification are restricted to whether the land is physically suited for the proposal, whether the use is consistent with local planning and zoning, or if the use is consistent with State and Federal programs.

Application Comments

Interested parties may submit comments regarding the specific use proposed in the application and plan of development, whether the BLM followed proper administrative procedures in reaching the decision, or any other factor not directly related to the suitability of the land for a municipal solid waste disposal site.

Any adverse comments will be reviewed by the State Director. In the absence of any adverse comments, the classification of the land described in this notice will become effective 60 days from the date of publication in the **Federal Register**. The lands will not be offered for conveyance until after the classification becomes effective.

Dated: August 6, 1997.

Ron Huntsinger,

Field Station Manager, Tonopah, NV.

[FR Doc. 97-21637 Filed 8-14-97; 8:45 am]

BILLING CODE 4310-HC-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID-957-1430-00]

Idaho: Filing of Plats of Survey

The plat of the following described land was officially filed in the Idaho State Office, Bureau of Land Management, Boise, Idaho, effective 9:00 a.m. August 7, 1997.

The plat representing the dependent resurvey of a portion of mineral survey No. 2890, Zephyr lode, T. 3 N., R. 3 E., Boise Meridian, Idaho, Group 1001, was accepted, August 7, 1997.

This survey was executed to meet certain administrative needs of the Bureau of Land Management. All inquiries concerning the survey of the above described land must be sent to the Chief, Cadastral Survey, Idaho State Office, Bureau of Land Management, 1387 South Vinnell Way, Boise, Idaho, 83709-1657.

Dated: August 7, 1997.

Duane E. Olsen,

Chief Cadastral Surveyor for Idaho.

[FR Doc. 97-21683 Filed 8-14-97; 8:45 am]

BILLING CODE 4310-GG-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID-957-1430-00]

Idaho: Filing of Plats of Survey

The plat of the following described land was officially filed in the Idaho State Office, Bureau of Land Management, Boise, Idaho, effective 9:00 a.m. August 7, 1997.

The plat representing the dependent resurvey of a portion of the east boundary, and of the subdivisional lines, and the subdivision of tract A in section 25 (now lots 1 and 2 of section 25), and of a metes-and-bounds survey within section 25, T. 8 S., R. 24 E., Boise Meridian, Idaho, Group 983, was accepted, August 7, 1997.

This survey was executed to meet certain administrative needs of the Bureau of Land Management. All inquiries concerning the survey of the above described land must be sent to the Chief, Cadastral Survey, Idaho State Office, Bureau of Land Management, 1387 South Vinnell Way, Boise, Idaho, 83709-1657.

Dated: August 7, 1997.

Duane E. Olsen,

Chief Cadastral Surveyor for Idaho.

[FR Doc. 97-21684 Filed 8-14-97; 8:45 am]

BILLING CODE 4310-GG-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID-957-1430-00]

Idaho: Filing of Plats of Survey

The plat of the following described land was officially filed in the Idaho State Office, Bureau of Land Management, Boise, Idaho, effective 9:00 a.m., August 7, 1997.

The plat representing the dependent resurvey of portions of the east boundary, and of the subdivisional lines, and the subdivision of section 25, T. 20 N., R. 3 E., Boise Meridian, Idaho, Group 961, was accepted, August 7, 1997.

This survey was executed to meet certain administrative needs of the US Forest Service. All inquiries concerning the survey of the above described land must be sent to the Chief, Cadastral Survey, Idaho State Office, Bureau of Land Management, 1387 South Vinnell Way, Boise, Idaho, 83709-1657.

Dated: August 7, 1997.

Duane E. Olsen,

Chief Cadastral Surveyor for Idaho.

[FR Doc. 97-21685 Filed 8-14-97; 8:45 am]

BILLING CODE 4310-GG-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID957-1430-00]

Idaho: Filing of Plats of Survey

The plat of the following described land was officially filed in the Idaho State Office, Bureau of Land Management, Boise, Idaho, effective 9:00 a.m. August 1, 1997.

The plat representing the dependent resurvey of portions of the subdivisional lines, the subdivision of section 27, and the survey of certain lots in sections 27 and 28, T. 3 N., R. 2 E., Boise Meridian, Idaho, Group 982, was accepted, August 1, 1997.

This survey was executed to meet certain administrative needs of the National Interagency Fire Center. All inquiries concerning the survey of the above described land must be sent to the Chief, Cadastral Survey, Idaho State Office, Bureau of Land Management, 1387 South Vinnell Way, Boise, Idaho, 83709-1657.

Dated: August 1, 1997.

Duane E. Olsen,

Chief Cadastral Surveyor for Idaho.

[FR Doc. 97-21688 Filed 8-14-97; 8:45 am]

BILLING CODE 4310-GG-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID-957-1430-00]

Idaho: Filing of Plats of Survey

The plat of the following described land was officially filed in the Idaho State Office, Bureau of Land Management, Boise, Idaho, effective 9:00 a.m. August 1, 1997.

The plat representing the dependent resurvey of a portion of the subdivisional lines, and the 1884 meanders of the right bank of the Snake River, the subdivision of section 28, and the survey of lots 10, 11, and 12 in section 28, T. 7S., R. 13 E., Boise Meridian, Idaho, Group 868, was accepted, August 1, 1997.

This survey was executed to meet certain administrative needs of the National Park Service. All inquiries concerning the survey of the above described land must be sent to the

Chief, Cadastral Survey, Idaho State Office, Bureau of Land Management, 1387 South Vinnell Way, Boise, Idaho, 83709-1657.

Dated: August 1, 1997.

Duane E. Olsen,

Chief Cadastral Surveyor for Idaho.

[FR Doc. 97-21689 Filed 8-14-97; 8:45 am]

BILLING CODE 4310-GG-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NM-952-07-1420-00]

Notice of Filing of Plat of Survey; New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The plat of survey described below will be officially filed in the New Mexico State Office, Bureau of Land Management, Santa Fe, New Mexico, on September 5, 1997.

New Mexico Principal Meridian, New Mexico:

Township 16 North, Range 7 East,
accepted August 4, 1997, for Group
942 NM.

If a protest against a survey, as shown on the above plat is received prior to the date of official filing, the filing will be stayed pending consideration of the protest. A plat will not be officially filed until the day after all protests have been dismissed and become final or appeals from the dismissal affirmed.

A person or party who wishes to protest against any of this survey must file a written protest with the State Director, Bureau of Land Management, stating that they wish to protest.

A statement of reasons for a protest may be filed with the notice of protest to the State Director, or the statement of reasons must be filed with the State Director within thirty (30) days after the protest is filed.

The above listed plat represents dependent resurveys, surveys, and subdivisions.

This plat will be available in the New Mexico State Office, Bureau of Land Management for public inspection, P.O. Box 27115, Santa Fe, New Mexico 87502-0115. Copies may be obtained from this office upon payment of \$1.10 per sheet.

Dated August 5, 1997.

John P. Bennett,

Chief Cadastral Surveyor For New Mexico.

[FR Doc. 97-21642 Filed 8-14-97; 8:45 am]

BILLING CODE 4310-FB-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[DEA #153F]

Controlled Substances: Revised Aggregate Production Quotas for 1997

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of final revised aggregate production quotas for 1997.

SUMMARY: This notice establishes revised 1997 aggregate production quotas for controlled substances in Schedules I and II of the Controlled Substances Act.

EFFECTIVE DATE: August 15, 1997.

FOR FURTHER INFORMATION CONTACT: Frank L. Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, D.C. 20537, Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION: Section 306 of the Controlled Substances Act (21 U.S.C. 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in Schedules I and II. This responsibility has been delegated to the Administrator of the DEA by § 0.100 of Title 28 of the Code of Federal Regulations. The Administrator, in turn, has redelegated this function to the Acting Deputy Administrator pursuant to § 0.104 of Title 28 of the Code of Federal Regulations.

On June 5, 1997, a notice of the proposed revised 1997 aggregate production quotas for controlled substances in Schedules I and II was published in the **Federal Register** (62 FR 30883). All interested parties were invited to comment on or object to these proposed aggregate production quotas on or before July 7, 1997.

Several companies commented that the revised 1997 aggregate production quotas for amphetamine, difenoxin, diphenoxylate, methadone intermediate, N-ethylamphetamine, noracymethadol, oxycodone, oxymorphone and pentobarbital were insufficient to provide for the estimated medical, scientific, research and industrial needs of the United States, for export requirements and for the establishment and maintenance of reserve stocks.

DEA has reviewed the involved companies' 1996 year-end inventories, their initial 1997 manufacturing quotas, 1997 export requirements and their actual and projected 1997 sales. Based on this data, the DEA has adjusted the revised 1997 aggregate production

quotas for difenoxin, diphenoxylate, N-ethylamphetamine, noracymethadol, oxycodone, oxymorphone and pentobarbital to meet the estimated medical, scientific, research and industrial needs of the United States.

Regarding amphetamine and methadone intermediate, the DEA has determined that no adjustments of the aggregate production quotas are necessary to meet the 1997 estimated medical, scientific, research and industrial needs of the United States.

Based on recent data submitted by two companies, DEA has adjusted the revised 1997 aggregate production quotas for hydromorphone and lysergic acid diethylamide (LSD) to meet the estimated medical, scientific, research and industrial needs of the United States.

The Office of Management and Budget has determined that notices of aggregate production quotas are not subject to centralized review under Executive Order 12866. This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this matter does not have sufficient Federalism implications to warrant the preparation of a Federalism Assessment.

The Acting Deputy Administrator hereby certifies that this action will have no significant impact upon small entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* The establishment of aggregate production quotas for Schedule I and II controlled substances is mandated by law and by international treaty obligations. Aggregate production quotas apply to approximately 200 DEA registered bulk and dosage from manufacturers of Schedule I and II controlled substances. The quotas are necessary to provide for the estimated medical, scientific, research and industrial needs of the United States, for export requirements and the establishment and maintenance of reserve stocks. While aggregate production quotas are of primary importance to large manufacturers, their impact upon small entities is neither negative nor beneficial. Accordingly, the Acting Deputy Administrator has determined that this action does not require a regulatory flexibility analysis.

Therefore, under the authority vested in the Attorney General by section 306 of the Controlled Substances Act of 1970 (21 U.S.C. 826), delegated to the Administrator of the DEA by § 0.100 of Title 28 of the Code of Federal Regulations, and redelegated to the Acting Deputy Administrator pursuant to § 0.104 of Title 28 of the Code of

Federal Regulations, the Acting Deputy Administrator hereby orders that the revised aggregate production quotas for

1997 for the following controlled substances, expressed in grams of

anhydrous acid or base, be established as follows:

Basic class	Established revised 1997 quotas
Schedule I	
2,5-Dimethoxyamphetamine	15,200,100
2,5-Dimethoxy-4-ethylamphetamine (DOET)	2
3-Methylfentanyl	14
3-Methylthiofentanyl	2
3,4-Methylenedioxyamphetamine (MDA)	22
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	27
3,4-Methylenedioxymethamphetamine (MDMA)	7
3,4,5-Trimethoxyamphetamine	2
4-Bromo-2,5-Dimethoxyamphetamine	2
4-Bromo-2,5-Dimethoxyphenethylamine (2-CB)	2
4-Methoxyamphetamine	17
4-Methylaminorex	2
4-Methyl-2,5-Dimethoxyamphetamine (DOM)	2
5-Methoxy-3,4-Methylenedioxyamphetamine	2
Acetyl-alpha-methylfentanyl	2
Acetylmethadol	7
Alpha-acetylmethadol	7
Alpha-ethyltryptamine	2
Alpha-methadol	2
Alpha-methylfentanyl	2
Alpha-methylthiofentanyl	2
Aminorex	7
Beta-acetylmethadol	2
Beta-hydroxyfentanyl	2
Beta-hydroxy-3-methylfentanyl	2
Beta-methadol	2
Bufotenine	2
Cathinone	9
Codeine-N-oxide	2
Difenoxin	21,000
Dihydromorphine	7
Ethylamine Analog of PCP	5
Heroin	2
Lysergic acid diethylamide (LSD)	57
Mescaline	7
Methaqualone	17
Methcathinone	11
Morphine-N-oxide	2
N-Ethylamphetamine	251,000
N-Hydroxy-3,4-Methylenedioxyamphetamine	2
N,N-Dimethyltryptamine	7
Noracetylmethadol	2
Norlevorphanol	2
Normethadone	7
Normorphine	7
Para-fluorofentanyl	2
Pholcodine	2
Psilocin	2
Psilocybin	2
Tetrahydrocannabinols	25,100
Thiofentanyl	2
Thiophene Analog of Phencyclidine	5
Schedule II	
1-Phenylcyclohexylamine	10
1-Piperidinocyclohexanecarbonitrile (PCC)	12
Alfentanil	9,300
Amobarbital	15
Amphetamine	3,137,000
Carfentanil	500
Cocaine	550,100
Codeine (for sale)	53,140,000
Codeine (for conversion)	19,679,000
Desoxyephedrine	1,393,000
1,361,000 grams of levodesoxyephedrine for use in a non-controlled, non-prescription product and 32,000 grams for methamphetamine.	
Dextropropoxyphene	116,469,000

Basic class	Established revised 1997 quotas
Dihydrocodeine	188,000
Diphenoxylate	2,247,000
Ecgonine (for conversion)	651,000
Ethylmorphine	12
Fentanyl	193,000
Glutethimide	2
Hydrocodone (for sale)	13,891,000
Hydrocodone (for conversion)	1,769,000
Hydromorphone	743,000
Isomethadone	12
Levo-alpha-acetylmethadol (LAAM)	356,000
Levomethorphan	2
Levorphanol	12,000
Meperidine	9,843,000
Methadone (for sale)	3,977,000
Methadone (for conversion)	364,000
Methadone Intermediate (for conversion)	5,275,000
Methamphetamine (for conversion)	723,000
Methylphenidate	13,824,000
Morphine (for sale)	11,126,000
Morphine (for conversion)	68,165,000
Noroxymorphone (for sale)	30,000
Noroxymorphone (for conversion)	2,000,000
Opium	575,000
Oxycodone (for sale)	8,323,000
Oxycodone (for conversion)	1,200
Oxymorphone	66,000
Pentobarbital	19,201,000
Phencyclidine	60
Phenmetrazine	2
Phenylacetone	10
Secobarbital	491,000
Sufentanil	1,000
Thebaine	9,325,000

Dated: August 11, 1997.

James S. Milford,

Acting Deputy Administrator.

[FR Doc. 97-21587 Filed 8-14-97; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review; Comment Request

August 12, 1997.

The Department of Labor (DOL) has submitted the following public information collection requests (ICRs) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chapter 35). A copy of each individual ICR, with applicable supporting documentation, may be obtained by calling the Department of Labor, Departmental Clearance Officer, Theresa M. O'Malley ((202) 219-5096 ext. 143) or by E-Mail to O'Malley-Theresa@dol.gov. Individuals who use a telecommunications device for the deaf (TTY/TDD) may call (202) 219-4720

between 1:00 p.m. and 4:00 p.m. Eastern time, Monday-Friday.

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for BLS, DM, ESA, ETA, MSHA, OSHA, PWBA, or VETS, Office of Management and Budget, Room 10235, Washington, DC 20503 ((202) 395-7316), within 30 days from the date of this publication in the **Federal Register**.

The OMB 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 submission of responses.

Agency: Mine Safety and Health Administration.

Title: Records of Preshift and Onshift Inspections of Slope and Shaft Areas.

OMB Number: 1219-0082

(reinstatement without change).

Frequency: Twice per shift.

Affected Public: Business or other for-profit.

Number of Respondents: 30.

Estimated Time Per Respondent: 1¼ hours.

Total Burden Hours: 12,705.

Total Annualized capital/startup costs: -0-.

Total annual costs (operating/maintaining systems or purchasing services): -0-.

Description: Requires coal mine operators to conduct examinations of slope and shaft areas for hazardous conditions, including tests for methane and oxygen deficiency, before and during each shift and before and after blasting. Records of the results of the inspections are required to be kept.

Agency: Employment and Training Administration.

Title: Workforce Flexibility (Work-Flex) Partnership Demonstration Program.

OMB Number: 1205-0375 (extension).

Frequency: On occasion.

Affected Public: Business or other for-profit.

Number of Respondents: 8.

Estimated Time Per Respondent: 160 hours.

Total Burden Hours: 1,280.

Total Annualized capital/startup costs: -0-.

Total annual costs (operating/maintaining systems or purchasing services): -0-.

Description: This request is related to the passage of P.L. 104-208 which permits states to submit statutory waiver proposals to the Department of Labor in order to overcome barriers to implementing reforms to their workforce development system.

Agency: Employment and Training Administration.

Title: Statutory Waiver Requests.

OMB Number: 1205-0376 (extension).

Frequency: On occasion.

Affected Public: Business or other for-profit.

Number of Respondents: 20.

Estimated Time Per Respondent: 80 hours.

Total Burden Hours: 1,600.

Total Annualized capital/startup costs: -0-.

Total annual costs (operating/maintaining systems or purchasing services): -0-.

Description: This request is related to the passage of P.L. 104-208 which permits states to submit statutory waiver proposals to the Department of Labor in order to overcome barriers to implementing reforms to their workforce development system.

Agency: Department Management, Office of the Chief Financial Officer.

Title: Salary Offset.

OMB Number: 1225-0038 (extension).

Frequency: On occasion.

Affected Public: Individuals or households.

Number of Respondents: 150.

Estimated Time Per Respondent: 1¼ hours.

Total Burden Hours: 375.

Total Annualized capital/startup costs: -0-.

Total annual costs (operating/maintaining systems or purchasing services): -0-.

Description: This information is collected from debtors to assist in determining whether an individual is actually indebted to the Department of Labor, and if so indebted, to evaluate the individual's ability to repay the debt.

Agency: Occupational Safety and Health Administration.

Title: Manufacturer's Certification of Modification of Construction Aerial Lifts (29 CFR Part 1926.453).

OMB Number: 1218-0000.

Frequency: On occasion.

Affected Public: Business or other for-profit.

Number of Respondents: 60.

Estimated Time Per Respondent: 5 minutes.

Total Burden Hours: 5 hours.

Total Annualized capital/startup costs: -0-.

Total annual costs (operating/maintaining systems or purchasing services): -0-.

Description: Employers are required to obtain a written certification of any field modifications made to aerial lifts. Such certifications must be prepared in writing by either the manufacturer of the aerial lift or a nationally recognized testing laboratory. The certification is to attest to the safety of the lift after modification.

Agency: Employment and Training Administration.

Title: Standardized Participant Information Report (SPIR) for JTPA Title IV, Section 402, Migrant and Seasonal Farmworker Programs.

OMB Number: 1205-0350 (reinstatement, without change).

Frequency: Quarterly; annually.

Affected Public: Not-for-profit institutions.

Number of Respondents: 53.

Estimated Time Per Respondent: 18 hours.

Total Burden Hours: 954.

Total Annualized capital/startup costs: -0-.

Total annual costs (operating/maintaining systems or purchasing services): \$265,000.

Description: This collection instrument is the Standardized Participant Information Record (SPIR) and instructions. A SPIR form is provided for optional use in gathering information at the grantee field office level. The SPIR itself is a computer file in a specified form which is submitted by grantees via diskette, modem or Internet which requires grantees to collect and report selected standardized information on participants of the Jobs Training Partnership Act, Title IV, Section 402—funded programs.

Theresa M. O'Malley,

Departmental Clearance Officer.

[FR Doc. 97-21667 Filed 8-14-97; 8:45 am]

BILLING CODE 4510-22-M

DEPARTMENT OF LABOR

Employment Standards Administration

Wage and Hour Division; Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR Part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR Part 1, Appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedes decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29

CFR Parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR Part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon And Related Acts," shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, N.W., Room S-3014, Washington, D.C. 20210.

Withdrawn General Wage Determination Decision

This is to advise all interested parties that the Department of Labor is withdrawing, from the date of this notice, General Wage Determination No. VA970051 dated February 14, 1997.

Agencies with construction projects pending, to which this wage decision would have been applicable, should utilize Wage Decision No. VA970032. Contracts for which bids have been opened shall not be affected by this notice. Also, consistent with 29 CFR 1.6(c)(2)(i)(A), when the opening of bids is less than ten (10) days from the date of this notice, this action shall be effective unless the agency finds that there is insufficient time to notify bidders of the change and the finding is documented in the contract file.

Modifications to General Wage Determination Decisions

The number of decisions listed in the Government Printing Office document entitled "General Wage Determinations Issued Under the Davis-Bacon and Related Acts" being modified are listed by Volume and State. Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I

Maine

ME970022 (Feb. 14, 1997)

Volume II

Maryland

MD970034 (Feb. 14, 1997)

MD970059 (Feb. 14, 1997)

Pennsylvania

PA970001 (Feb. 14, 1997)

PA970002 (Feb. 14, 1997)

PA970004 (Feb. 14, 1997)

PA970005 (Feb. 14, 1997)

PA970006 (Feb. 14, 1997)

PA970018 (Feb. 14, 1997)

PA970026 (Feb. 14, 1997)

PA970030 (Feb. 14, 1997)

PA970031 (Feb. 14, 1997)

PA970042 (Feb. 14, 1997)

Virginia

VA970004 (Feb. 14, 1997)

VA970005 (Feb. 14, 1997)

VA970032 (Feb. 14, 1997)

Volume III

Georgia

GA970003 (Feb. 14, 1997)

GA970004 (Feb. 14, 1997)

GA970022 (Feb. 14, 1997)

GA970032 (Feb. 14, 1997)

GA970033 (Feb. 14, 1997)

GA970065 (Feb. 14, 1997)

GA970073 (Feb. 14, 1997)

GA970084 (Feb. 14, 1997)

GA970085 (Feb. 14, 1997)

GA970086 (Feb. 14, 1997)

GA970087 (Feb. 14, 1997)

GA970088 (Feb. 14, 1997)

Volume IV

Illinois

IL970001 (Feb. 14, 1997)

IL970002 (Feb. 14, 1997)

IL970006 (Feb. 14, 1997)

IL970007 (Feb. 14, 1997)

IL970008 (Feb. 14, 1997)

IL970009 (Feb. 14, 1997)

IL970011 (Feb. 14, 1997)

IL970014 (Feb. 14, 1997)

IL970016 (Feb. 14, 1997)

IL970017 (Feb. 14, 1997)

IL970026 (Feb. 14, 1997)

IL970049 (Feb. 14, 1997)

Indiana

IN970001 (Feb. 14, 1997)

IN970002 (Feb. 14, 1997)

IN970003 (Feb. 14, 1997)

IN970004 (Feb. 14, 1997)

IN970006 (Feb. 14, 1997)

Michigan

MI970002 (Feb. 14, 1997)

MI970062 (Feb. 14, 1997)

Wisconsin

WI970001 (Feb. 14, 1997)

WI970002 (Feb. 14, 1997)

WI970003 (Feb. 14, 1997)

WI970004 (Feb. 14, 1997)

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WI970037 (Feb. 14, 1997)

WI970039 (Feb. 14, 1997)

WI970041 (Feb. 14, 1997)

WI970049 (Feb. 14, 1997)

WI970066 (Feb. 14, 1997)

WI970067 (Feb. 14, 1997)

Volume V

Iowa

IA970005 (Feb. 14, 1997)

IA970013 (Feb. 14, 1997)

IA970016 (Feb. 14, 1997)

IA970019 (Feb. 14, 1997)

IA970024 (Feb. 14, 1997)

Kansas

KS970008 (Feb. 14, 1997)

KS970012 (Feb. 14, 1997)

Nebraska

NE970001 (Feb. 14, 1997)

NE970003 (Feb. 14, 1997)

NE970009 (Feb. 14, 1997)

NE970010 (Feb. 14, 1997)

NE970011 (Feb. 14, 1997)

NE970019 (Feb. 14, 1997)

NE970038 (Feb. 14, 1997)

NE970058 (Feb. 14, 1997)

Texas

TX970003 (Feb. 14, 1997)

TX970005 (Feb. 14, 1997)

TX970010 (Feb. 14, 1997)

TX970054 (Feb. 14, 1997)

TX970063 (Feb. 14, 1997)

TX970096 (Feb. 14, 1997)

Volume VI

Colorado

CO970004 (Feb. 14, 1997)

CO970018 (Feb. 14, 1997)

Idaho

ID970001 (Feb. 14, 1997)

Washington

WA970001 (Feb. 14, 1997)

WA970002 (Feb. 14, 1997)

WA970003 (Feb. 14, 1997)

WA970004 (Feb. 14, 1997)

WA970005 (Feb. 14, 1997)

WA970006 (Feb. 14, 1997)

WA970007 (Feb. 14, 1997)

WA970008 (Feb. 14, 1997)

WA970010 (Feb. 14, 1997)

WA970011 (Feb. 14, 1997)

WA970023 (Feb. 14, 1997)

Volume VII

California

CA970001 (Feb. 14, 1997)

CA970002 (Feb. 14, 1997)

CA970028 (Feb. 14, 1997)

CA970029 (Feb. 14, 1997)

CA970030 (Feb. 14, 1997)
 CA970031 (Feb. 14, 1997)
 CA970032 (Feb. 14, 1997)
 CA970033 (Feb. 14, 1997)
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 CA970036 (Feb. 14, 1997)
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 CA970041 (Feb. 14, 1997)
 CA970042 (Feb. 14, 1997)
 CA970043 (Feb. 14, 1997)
 CA970044 (Feb. 14, 1997)
 CA970045 (Feb. 14, 1997)
 CA970046 (Feb. 14, 1997)
 CA970047 (Feb. 14, 1997)
 CA970048 (Feb. 14, 1997)

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon and Related Acts". This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country.

The general wage determinations issued under the Davis-Bacon and related Acts are available electronically by subscription to the FedWorld Bulletin Board System of the National Technical Information Service (NTIS) of the U.S. Department of Commerce at (703) 487-4630.

Hard-copy subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, (202) 512-1800.

When ordering hard-copy subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the seven separate volumes, arranged by State. Subscriptions include an annual edition (issued in January or February) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates are distributed to subscribers.

Signed at Washington, D.C. this 8th day of August 1997.

Margaret Washington,

Acting Chief, Branch of Construction Wage Determinations.

[FR Doc. 97-21385 Filed 8-14-97; 8:45 am]

BILLING CODE 4510-27-P-M

DEPARTMENT OF LABOR

Bureau of Labor Statistics

Proposed Collection; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance 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 Bureau of Labor Statistics (BLS) is soliciting comments concerning the proposed reinstatement of the "CPS Displaced Worker and Job Tenure Supplement."

A copy of the proposed information collection request (ICR) can be obtained by contacting the individual listed below in the ADDRESSES section of this notice.

DATES: Written comments must be submitted to the office listed in the ADDRESSES section below on or before October 14, 1997.

The Bureau of Labor Statistics 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: Send comments to Karin G. Kurz, BLS Clearance Officer, Division of

Management Systems, Bureau of Labor Statistics, Room 3255, 2 Massachusetts Avenue, NE., Washington, DC 20212. Ms. Kurz can be reached on 202-606-7628 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

The Employment and Training Administration (ETA) of the Department of Labor sponsors the Displaced Workers supplement to the Current Population Survey (CPS). Data on displaced workers were first collected in January 1984. Subsequent displaced worker surveys have been conducted biennially. In addition to the information on worker displacement, the February 1998 CPS supplement also will collect information on job tenure.

The information will be used to determine the size and nature of the population affected by job displacements and, hence, the needs and scope of ETA programs serving adult displaced workers. The information collected also will be used to assess employment stability by determining the length of time workers have been with their current employer. In addition, data on job tenure for all workers are needed to calculate the incidence of displacement among various worker groups so that comparisons can be made over time and among different affected groups. Combining the questions on displacement and tenure will enable analysts to obtain a more complete picture of employment stability.

II. Current Actions

The questions concerning displacement among workers will help define the size of the readjustment problem faced by individual workers and the economy including: (a) Workers who have lost their jobs or have received notice that they soon will lose their jobs due to a permanent plant closing; (b) laid-off workers who are unlikely to return to their previous industry or occupation; and (c) the long-term unemployed with little prospect of reemployment. Policy planning has to take into account the industries with the most severe displacement problem and the retraining needs of affected workers.

This supplement also will provide data regarding:

1. The economic impact of job displacements. For those workers who have been reemployed, data will be collected to compare current earnings with those from the lost job.
2. Information on the receipt of unemployment compensation, the loss of health insurance coverage, and the

time spent without a job. In combination, these supplemental data will provide the information needed to assess the economic hardship experienced by displaced workers.

3. Types of jobs that displaced workers have been able to find. This will assist in developing training programs that will provide other displaced workers with the skills necessary to adjust to the changing economic environment.

4. The extent to which displaced workers received advance notice of job cutbacks or the closing of their plant or business. The President, Congress, and private organizations have shown significant interest in this area.

5. The length of time workers (including those who have not been displaced) have been with their current employer. Tenure data are used to calculate displacement rates for long-tenured workers so that comparisons can be made over time and among different worker groups. Information on job tenure also is important because of the effect seniority has on wage levels, the receipt of employee benefits such as vacations and pensions, and other facets of the employment relationship.

Type of Review: Reinstatement, with change, of previously approved collection for which approval has expired.

Agency: Bureau of Labor Statistics.

Title: CPS Displaced Worker and Job Tenure Supplement.

OMB Number: 1220-0104.

Affected Public: Individuals or households.

Total Respondents: 48,000.

Frequency: One-time.

Total Responses: 48,000.

Average Time Per Response: 8 minutes.

Estimated Total Burden Hours: 6,400 hours.

Total Burden Cost (capital/startup): \$0.

Total Burden Cost (operating/maintenance): \$0.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they also will become a matter of public record.

Signed at Washington, D.C., this 11th day of August 1997.

Ausie B. Grigg, Jr.,

Acting Chief, Division of Management Systems, Bureau of Labor Statistics.

[FR Doc. 97-21666 Filed 8-14-97; 8:45 am]

BILLING CODE 4510-14-M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts; Combined Arts Panel

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), as amended, notice is hereby given that a meeting of the Combined Arts Advisory Panel, Music Section A (Creation & Presentation category) to the National Council on the Arts will be held on September 8-12, 1997. The panel will meet from 10:00 a.m. to 6:00 p.m. on September 8; from 9:00 a.m. to 6:00 p.m. on September 9 and 10; from 9:00 a.m. to 4:00 p.m. on September 11; and from 9:00 a.m. to 12:00 p.m. on September 12 in Room 730 at the Nancy Hanks Center, 1100 Pennsylvania Avenue, N.W., Washington, D.C., 20506. A portion of this meeting, from 2:00 p.m. to 4:00 p.m. on September 11, will be open to the public for a policy discussion on guidelines, Leadership Initiatives, Millennium projects, planning, and field needs and trends.

The remaining portions of this meeting, from 10:00 a.m. to 6:00 p.m. on September 8; from 9:00 a.m. to 6:00 p.m. on September 9 and 10; from 9:00 a.m. to 2:00 p.m. on September 11 and from 9:00 a.m. to 12:00 p.m. on September 12 are for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman of March 31, 1997, these sessions will be closed to the public pursuant to subsection (c)(4)(6) and (9)(B) of section 552b of Title 5, United States Code.

Any person may observe meetings, or portions thereof, of advisory panels which are open to the public, and may be permitted to participate in the panel's discussions at the discretion of the panel chairman and with the approval of the full-time Federal employee in attendance.

If you need special accommodations due to a disability, please contact the Office of AccessAbility, National Endowment for the Arts, 1100 Pennsylvania Avenue, N.W., Washington, D.C. 20506, 202/682-5532, TDY-TDD 202/682-5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Kathy Plowitz-Worden, Committee Management Officer, National

Endowment for the Arts, Washington, D.C., 20506, or call 202/682-5691.

Dated: August 12, 1997.

Kathy Plowitz-Worden,

Panel Coordinator, Panel Operations, National Endowment for the Arts.

[FR Doc. 97-21675 Filed 8-14-97; 8:45 am]

BILLING CODE 7537-01-M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts; Combined Arts Panel

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), as amended, notice is hereby given that a meeting of the Combined Arts Advisory Panel, Media Arts Section A (Creation & Presentation category) to the National Council on the Arts will be held on September 25-26, 1997. The panel will meet from 9:00 a.m. to 5:30 p.m. on September 25 and from 9:00 a.m. to 4:00 p.m. on September 26 in Room 716 at the Nancy Hanks Center, 1100 Pennsylvania Avenue, N.W., Washington, D.C., 20506. A portion of this meeting, from 1:00 p.m. to 2:30 p.m. on September 26, will be open to the public for a policy discussion on guidelines, Leadership Initiatives, Millennium projects, planning, and field needs and trends.

The remaining portions of this meeting, from 9:00 a.m. to 5:30 p.m. on September 25 and from 9 a.m. to 12:00 p.m. and 2:30 p.m. to 4:00 p.m. on September 26, are for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman of March 31, 1997, these sessions will be closed to the public pursuant to subsection (c)(4) (6) and (9)(B) of section 552b of Title 5, United States Code.

Any person may observe meetings, or portions thereof, of advisory panels which are open to the public, and may be permitted to participate in the panel's discussions at the discretion of the panel chairman and with the approval of the full-time Federal employee in attendance.

If you need special accommodations due to a disability, please contact the Office of AccessAbility, National Endowment for the Arts, 1100 Pennsylvania Avenue, N.W., Washington, D.C. 20506, 202/682-5532,

TDY–TDD 202/682–5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Kathy Plowitz-Worden, Committee Management Officer, National Endowment for the Arts, Washington, D.C., 20506, or call 202/682–5691.

Dated: August 14, 1997.

Kathy Plowitz-Worden,

*Panel Coordinator, Panel Operations,
National Endowment for the Arts.*

[FR Doc. 97–21676 Filed 8–14–97; 8:45 am]

BILLING CODE 7537–01–M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment of the Arts; Combined Arts Panel

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), as amended, notice is hereby given that a meeting of the Combined Arts Advisory Panel, Museum and Visual Arts Sections (Education & Access category) to the National Council on the Arts will be held on September 3–5, 1997. The panel will meet from 9:00 a.m. to 6:00 p.m. on September 3 and 4, and from 9:00 a.m. to 3:30 p.m. on September 5 in Room 716 at the Nancy Hanks Center, 1100 Pennsylvania Avenue, N.W., Washington, D.C., 20506. A portion of this meeting, from 9:00 a.m. to 11:30 a.m. on September 5, will be open to the public for a policy discussion on guidelines, Leadership Initiatives, Millennium projects, planning, and field needs and trends.

The remaining portions of this meeting, from 9:00 a.m. to 6:00 p.m. on September 3 and 4 from 12:30 p.m. to 3:30 p.m. on September 5 are for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman of March 31, 1997, these sessions will be closed to the public pursuant to subsection (c) (4), (6) and (9)(B) of section 552b of Title 5, United States Code.

Any person may observe meetings, or portions thereof, of advisory panels which are open to the public, and may be permitted to participate in the panel's discussions at the discretion of the panel chairman and with the approval of the full-time Federal employee in attendance.

If you need special accommodations due to a disability, please contact the Office of AccessAbility, National Endowment for the Arts, 1100 Pennsylvania Avenue, N.W., Washington, D.C. 20506, 202/682–5532, TDY–TDD 202/682–5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Kathy Plowitz-Worden, Committee Management Officer, National Endowment for the Arts, Washington, D.C., 20506, or call 202/682–5691.

Dated: August 12, 1997.

Kathy Plowitz-Worden,

*Panel Coordinator, Panel Operations,
National Endowment for the Arts.*

[FR Doc. 97–21677 Filed 8–14–97; 8:45 am]

BILLING CODE 7537–01–M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts; Fellowships Panel

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), as amended, notice is hereby given that a meeting of the Fellowships Advisory Panel, Literature Section (Creative Writing Fellowships, Literary Publishing category) to the National Council on the Arts will be held on September 17–19, 1997. The panel will meet from 9:00 a.m. to 6:30 p.m. on September 17 and 18 and from 9:00 a.m. to 5:00 p.m. on September 19 in Room M–07 at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW., Washington, DC 20506. A portion of this meeting, from 9:00 a.m. to 10:30 a.m. on September 19, will be open to the public for a policy and guidelines discussion.

The remaining portions of this meeting, from 9:00 a.m. to 6:30 p.m. on September 17 and 18 and from 10:30 a.m. to 5:00 p.m. on September 19, are for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman of March 31, 1997, these sessions will be closed to the public pursuant to subsection (c) (4), (6) and (9)(B) of section 552b of Title 5, United States Code.

Any person may observe meetings, or portions thereof, of advisory panels which are open to the public, and may be permitted to participate in the

panel's discussions at the discretion of the panel chairman and with the approval of the full-time Federal employee in attendance.

If you need special accommodations due to a disability, please contact the Office of AccessAbility, National Endowment for the Arts, 1100 Pennsylvania Avenue, NW., Washington, DC 20506, 202/682–5532, TDY–TDD 202/682–5496 at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Kathy Plowitz-Worden, Committee Management Officer, National Endowment for the Arts, Washington, DC 20506, or call 202/682–5691.

Dated: August 12, 1997.

Kathy Plowitz-Worden,

*Panel Coordinator, Panel Operations,
National Endowment for the Arts.*

[FR Doc. 97–21674 Filed 8–14–97; 8:45 am]

BILLING CODE 7537–01–M

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–369 and 50–370]

Duke Power Company; McGuire Nuclear Station, Units 1 and 2; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of amendments to Facility Operating License Nos. NPF–9 and NPF–17, issued to Duke Power Company (the licensee), for operation of the McGuire Nuclear Station, Units 1 and 2, located in Mecklenburg County, North Carolina.

Environmental Assessment

Identification of Proposed Action

The proposed action would amend the licenses to reflect the licensee's name change from "Duke Power Company" to "Duke Energy Corporation."

The proposed action is in response to the licensee's application dated June 12, 1997.

The Need for the Proposed Action

Duke Power Company changed its name to "Duke Energy Corporation." The facility operating licenses for McGuire indicate the name of the licensee as "Duke Power Company," and therefore need to be amended to substitute the new name of the licensee. The proposed action is purely administrative.

Environmental Impacts of the Proposed Action

The Commission has completed its evaluation of the proposed action and concludes that there is no significant environmental impact if the amendments are granted. No changes will be made to the design and licensing bases, or procedures of the two units at the McGuire Nuclear Station. Other than the name change, no other changes will be made to the facility operating licenses, including the Technical Specifications.

The change will not increase the probability or consequences of accidents, no changes are being made in the types of any effluents that may be released offsite, and there is no significant increase in the allowable individual or cumulative occupational radiation exposure. Accordingly, the Commission concludes that there are no significant radiological environmental impacts associated with the proposed action.

With regard to potential nonradiological impacts, the proposed action does not affect nonradiological plant effluents and has no other environmental impact. Accordingly, the Commission concludes that there are no significant nonradiological environmental impacts associated with the proposed action.

Alternatives to the Proposed Action

Since the Commission has concluded there is no measurable environmental impact associated with the proposed action, any alternatives with equal or greater environmental impact need not be evaluated. As an alternative to the proposed action, the staff considered denial of the proposed action. Denial of the application would result in no change in current environmental impacts. The environmental impacts of the proposed action and the alternative action are similar.

Alternative Use of Resources

This action does not involve the use of any resources not previously considered in the Final Environmental Statement related to the McGuire Nuclear Station.

Agencies and Persons Contacted

In accordance with its stated policy, on August 1, 1997, the staff consulted with the North Carolina State official, Richard Frye of the Division of Protection, North Carolina Department of Environment, Health, and Natural Resources, regarding the environmental impact of the proposed amendments. The State official had no comments.

Finding of No Significant Impact

Based upon the foregoing environmental assessment, the Commission concludes that the proposed amendments will not have a significant effect on the quality of the human environment. Accordingly, the Commission has determined not to prepare an environmental impact statement for the proposed amendments.

For further details with respect to the proposed action, see the licensee's request for the amendments dated June 12, 1997, which is available for public inspection at the Commission's Public Document Room, The Gelman Building, 2120 L Street, NW., Washington DC, and at the local public document room located at the J. Murrey Atkins Library, University of North Carolina at Charlotte, 9201 University City Boulevard, Charlotte, North Carolina.

Dated at Rockville, Maryland, this 8th day of August 1997.

For the Nuclear Regulatory Commission.

Ngoc B. Le,

Acting Director, Project Directorate II-2, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 97-21680 Filed 8-14-97; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION**Advisory Committee on Reactor Safeguards; Meeting Notice**

In accordance with the purposes of Sections 29 and 182b. of the Atomic Energy Act (42 U.S.C. 2039, 2232b), the Advisory Committee on Reactor Safeguards will hold a meeting on September 3-5, 1997, in Conference Room T-2B3, 11545 Rockville Pike, Rockville, Maryland. The date of this meeting was previously published in the **Federal Register** on Thursday, January 23, 1997 (62 FR 3539).

Wednesday, September 3, 1997

8:30 a.m.-8:45 a.m.: Opening Remarks by the ACRS Chairman (Open)—

The ACRS Chairman will make opening remarks regarding conduct of the meeting and comment briefly regarding items of current interest. During this session, the Committee will discuss priorities for preparation of ACRS reports.

8:45 a.m.-9:45 a.m.: Staff Action Plan to Improve the Senior Management Meeting Process, SECY-97-072 (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff, as needed, regarding

the action plan to improve the Senior Management Meeting Process.

9:45 a.m.-10:45 a.m.: Draft Regulatory Guide DG-1069: Fire Protection Program for Permanently Shutdown and Decommissioning Nuclear Plants (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the Draft Regulatory Guide DG-1069 on the fire protection program for permanently shutdown and decommissioning nuclear plants.

11:00 a.m.-12:30 p.m.: Proposed Generic Letter and Regulatory Guide Associated with Steam Generator Integrity (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the proposed Generic Letter and Regulatory Guide associated with steam generator integrity.

1:30 p.m.-2:00 p.m.: Reporting Reliability and Availability Information for Risk-Significant Systems and Equipment (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff, as needed, regarding the voluntary approach proposed by the industry for reporting reliability and availability information for risk-significant systems and equipment.

2:00 p.m.-2:30 p.m.: NRC Programs for Risk-Based Analysis of Reactor Operating Experience and Special Studies (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff, as needed, regarding the NRC Programs for Risk-Based Analysis of Reactor Operating Experience as well as the results of several special studies performed by the staff, including those related to auxiliary feedwater, Westinghouse reactor protection systems, loss of offsite power, initiating events, reactor core injection cooling, high pressure core injection, and fire events.

2:30 p.m.-3:30 p.m.: Site-Specific Safety Goals (Open)—The Committee will hear presentations by and hold discussions with an ACRS Senior Fellow, and representatives of the NRC staff, as needed, regarding the use of site-specific safety goals.

3:45 p.m.-4:15 p.m.: Use of Uncertainty Versus Point Values in the PRA-Related Decisionmaking Process (Open)—The Committee will hear a report by the Chairman of the

Probabilistic Risk Assessment Subcommittee regarding matters discussed at the August 28–29, 1997 Subcommittee meeting.
 4:15 p.m.–7:00 p.m.: *Preparation of ACRS Reports* (Open)—The Committee will discuss proposed ACRS reports on matters considered during this meeting.

Thursday, September 4, 1997

8:30 a.m.–8:35 a.m.: *Opening Remarks by the ACRS Chairman* (Open)—The ACRS Chairman will make opening remarks regarding conduct of the meeting.

8:35 a.m.–10:15 a.m.: *Meeting with the NRC Executive Director for Operations* (Open)—The Committee will meet with the NRC Executive Director for Operations regarding items of mutual interest, including the following:

- Human Performance Program Plan
- Research Program
- Oversight of DOE facilities/Direction Setting Issue #2
- Development of risk-informed regulation
- Role of ACRS in resolving technical differences between NRC staff and industry

10:30 a.m.–11:00 a.m.: *BWR Pressure Vessel Shell Weld Inspections* (Open)—The Committee will hear a report by the Chairman of the Materials and Metallurgy Subcommittee regarding issues discussed/raised at the August 26, 1997 Subcommittee meeting associated with BWR pressure vessel shell weld inspections.

11:00 a.m.–11:15 a.m.: *Subcommittee Report* (Open)—The Committee will hear a report by the Chairman of the Thermal-Hydraulic Phenomena Subcommittee regarding the items discussed during the July 29–30, 1997 Subcommittee meeting.

11:15 a.m.–11:30 a.m.: *Subcommittee Report* (Open)—The Committee will hear a report by the Chairman of the Regulatory Policies and Practices Subcommittee regarding matters discussed during the August 27, 1997 Subcommittee meeting.

11:30 a.m.–12:00 Noon: *Future ACRS Activities* (Open)—The Committee will discuss the recommendations of the Planning and Procedures Subcommittee regarding items proposed for consideration by the full Committee during future meetings.

1:00 p.m.–2:45 p.m.: *Proposed Rule on Shutdown and Fuel Storage Pool Operations* (Open)—The Committee will hear presentations by and hold discussions with representatives of

the NRC staff regarding the proposed rule on shutdown and fuel storage pool operations.
 3:00 p.m.–7:00 p.m.: *Preparation of ACRS Reports* (Open)—The Committee will discuss proposed ACRS reports on matters considered during this meeting.

Friday, September 5, 1997

8:30 a.m.–8:35 a.m.: *Opening Remarks by the ACRS Chairman* (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

8:35 a.m.–10:30 a.m.: *Improper Control Rod Movement During Shutdown at Zion Unit 1, and Nonconservative Operations During Isolation of Recirculation Pump Seal Leak at Clinton* (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding improper control rod movement during shutdown at Zion Unit 1, nonconservative operations during isolation of recirculation pump seal leak at the Clinton Nuclear Power Plant, and human/organizational performance issues associated with these incidents.

10:45 a.m.–11:00 a.m.: *Reconciliation of ACRS Comments and Recommendations* (Open)—The Committee will discuss responses from the NRC Executive Director for Operations to comments and recommendations included in recent ACRS reports, including those on the Proposed Regulatory Approach associated with Steam Generator Integrity, Inclusion of a Containment Spray System in the AP600 design, and proposed Final Revisions to 10 CFR Part 26, Fitness-For-Duty Program Requirements.

11:00 a.m.–11:30 a.m.: *Report of the Planning and Procedures Subcommittee* (Open/Closed)—The Committee will hear a report of the Planning and Procedures Subcommittee on matters related to the conduct of ACRS business, qualifications of candidates nominated for appointment to the ACRS, and organizational and personnel matters relating to the ACRS.

[**Note:** A portion of this session may be closed to discuss organizational and personnel matters that relate solely to the internal personnel rules and practices of this Advisory Committee, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.]

12:30 p.m.–3:30 p.m.: *Preparation of ACRS Reports* (Open)—The

Committee will complete its discussion of proposed ACRS reports on matters considered during this meeting.

3:45 p.m.–4:30 p.m.: *Strategic Planning* (Open)—The Committee will continue its discussion of items of significant importance to NRC, including rebaselining of the Committee activities for FY 1998.

4:30 p.m.–4:45 p.m.: *Miscellaneous* (Open)—The Committee will discuss matters related to the conduct of Committee activities and specific issues that were not completed during previous meetings, as time and availability of information permit.

Procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 1, 1996 (61 FR 51310). In accordance with these procedures, oral or written statements may be presented by members of the public and representatives of the nuclear industry, electronic recordings will be permitted only during the open portions of the meeting, and questions may be asked only by members of the Committee, its consultants, and staff. Persons desiring to make oral statements should notify Mr. Sam Duraiswamy, Chief, Nuclear Reactors Branch, at least five days before the meeting, if possible, so that appropriate arrangements can be made to allow the necessary time during the meeting for such statements. Use of still, motion picture, and television cameras during this meeting may be limited to selected portions of the meeting as determined by the Chairman. Information regarding the time to be set aside for this purpose may be obtained by contacting the Chief of the Nuclear Reactors Branch prior to the meeting. In view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the Chief of the Nuclear Reactors Branch if such rescheduling would result in major inconvenience.

In accordance with Subsection 10(d) P.L. 92–463, I have determined that it is necessary to close portions of this meeting noted above to discuss matters that relate solely to the internal personnel rules and practices of this Advisory Committee per 5 U.S.C. 552b(c)(2), and to discuss information the release of which would constitute a clearly unwarranted invasion of personal privacy per 5 U.S.C. 552b(c)(6).

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the

Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor, can be obtained by contacting Mr. Sam Duraiswamy, Chief, Nuclear Reactors Branch (telephone 301/415-7364), between 7:30 a.m. and 4:15 p.m. EDT.

ACRS meeting notices, meeting transcripts, and letter reports are now available on FedWorld from the "NRC MAIN MENU." The Direct Dial Access number to FedWorld is (800) 303-9672 or ftp.fedworld. These documents and the meeting agenda are also available for downloading or reviewing on the internet at <http://www.nrc.gov/ACRSACNW>.

Dated: August 11, 1997.

John C. Hoyle,

Acting Advisory Committee Management Officer.

[FR Doc. 97-21681 Filed 8-14-97; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50-508 and 50-509]

Washington Nuclear Units 3 and 5 Closing of Local Public Document Room

Notice is hereby given that the Nuclear Regulatory Commission (NRC) is closing the local public document room (LPDR) for records pertaining to the Washington Public Power Supply System's Washington Nuclear Units 3 and 5 (WPPSS) located at the W.H. Abel Memorial Library, Montesano, Washington, effective August 15, 1997.

The W.H. Abel Memorial Library has served as the LPDR for WPPSS Units 3 and 5 for 23 years. In a letter dated May 28, 1997, the community librarian officially informed the NRC that they no longer wish to serve as the LPDR. NRC has made the decision to officially close the WPPSS Units 3 and 5 LPDR because none of the libraries in the vicinity of the Satsop, Washington site are interested in maintaining the document collection, no facility was ever constructed on the site, and there has been no demonstrated local public interest in the LPDR materials for a number of years. Therefore, effective August 15, 1997, the LPDR will be closed.

Persons now interested in information pertaining to this facility or any other NRC activity may contact the NRC Public Document Room by calling toll-free 1-800-397-4209 or writing to NRC Public Document Room, Washington, DC 20555-0001.

Dated at Rockville, Maryland, this 11th day of August, 1997.

For the Nuclear Regulatory Commission.

Russell A. Powell,

Chief, Freedom of Information/Local Public Document Room Branch, Office of Information Resources Management.

[FR Doc. 97-21679 Filed 8-14-97; 8:45 am]

BILLING CODE 7590-01-P

PENSION BENEFIT GUARANTY CORPORATION

Interest Assumption for Determining Variable-Rate Premium; Interest Assumptions for Multiemployer Plan Valuations Following Mass Withdrawal

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of interest rates and assumptions.

SUMMARY: This notice informs the public of the interest rates and assumptions to be used under certain Pension Benefit Guaranty Corporation regulations. These rates and assumptions are published elsewhere (or are derivable from rates published elsewhere), but are collected and published in this notice for the convenience of the public. Interest rates are also published on the PBGC's home page (<http://www.pbtc.gov>).

DATES: The interest rate for determining the variable-rate premium under part 4006 applies to premium payment years beginning in August 1997. The interest assumptions for performing multiemployer plan valuations following mass withdrawal under part 4281 apply to valuation dates occurring in September 1997.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202-326-4024 (202-326-4179 for TTY and TDD).

SUPPLEMENTARY INFORMATION:

Variable-Rate Premiums

Section 4006(a)(3)(E)(iii)(II) of the Employee Retirement Income Security Act of 1974 (ERISA) and § 4006.4(b)(1) of the PBGC's regulation on Premium Rates (29 CFR part 4006) prescribe use of an assumed interest rate in determining a single-employer plan's variable-rate premium. The rate is the "applicable percentage" (described in the statute and the regulation) of the annual yield on 30-year Treasury securities for the month preceding the beginning of the plan year for which

premiums are being paid (the "premium payment year"). The yield figure is reported in Federal Reserve Statistical Releases G.13 and H.15.

For plan years beginning before July 1, 1997, the applicable percentage of the 30-year Treasury yield was 80 percent. The Retirement Protection Act of 1994 (RPA) amended ERISA section 4006(a)(3)(E)(iii)(II) to provide that the applicable percentage is 85 percent for plan years beginning on or after July 1, 1997, through (at least) plan years beginning before January 1, 2000.

However, under section 774(c) of the RPA, the application of the amendment is deferred for certain regulated public utility (RPU) plans for as long as six months. The applicable percentage for RPU plans will therefore remain 80 percent for plan years beginning before January 1, 1998. (The rules governing the applicable percentages for "partial" RPU plans are described in § 4006.5(g) of the premium rates regulation.)

For plans for which the applicable percentage is 85 percent, the assumed interest rate to be used in determining variable-rate premiums for premium payment years beginning in August 1997 is 5.53 percent (*i.e.*, 85 percent of the 6.51 percent yield figure for July 1997).

The following table lists the assumed interest rates to be used in determining variable-rate premiums for premium payment years beginning between September 1996 and August 1997. The rates for July and August 1997 in the table reflect an applicable percentage of 85 percent and thus apply only to non-RPU plans. However, the rates for months before July 1997, which reflect an applicable percentage of 80 percent, apply to RPU (and "partial" RPU) plans as well as to non-RPU plans.

For premium payment years beginning in	The assumed interest rate is
September 1996	5.47
October 1996	5.62
November 1996	5.45
December 1996	5.18
January 1997	5.24
February 1997	5.46
March 1997	5.35
April 1997	5.54
May 1997	5.67
June 1997	5.55
July 1997	5.75
August 1997	5.53

For premium payment years beginning in August 1997, the assumed interest rate to be used in determining variable-rate premiums for RPU plans (determined using an applicable percentage of 80 percent) is 5.21 percent. For "partial" RPU plans, the assumed interest rates to be used in determining variable-rate premiums can be computed by applying the rules in § 4006.5(g) of the premium rates regulation. The PBGC's premium payment instruction booklet also describes these rules and provides a worksheet for computing the assumed rate.

Multiemployer Plan Valuations Following Mass Withdrawal

The PBGC's regulation on Duties of Plan Sponsor Following Mass Withdrawal (29 CFR part 4281) prescribes the use of interest assumptions under the PBGC's regulation on Allocation of Assets in Single-employer Plans (29 CFR part 4044). The interest assumptions applicable to valuation dates in September 1997 under part 4044 are contained in an amendment to part 4044 published elsewhere in today's **Federal Register**. Tables showing the assumptions applicable to prior periods are codified in appendix B to 29 CFR part 4044.

Issued in Washington, D.C., on this 8th day of August 1997.

David M. Strauss,

Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 97-21598 Filed 8-14-97; 8:45 am]

BILLING CODE 7708-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 35-26753]

Filings Under the Public Utility Holding Company Act of 1935, as Amended ("Act")

August 8, 1997.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated thereunder. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendments thereto is/are available for public inspection through the Commission's Office of Public Reference.

Interested persons wishing to comment or request a hearing on the

application(s) and/or declaration(s) should submit their views in writing by September 2, 1997, to the Secretary, Securities and Exchange Commission, Washington, DC 20549, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. Any request for hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After said date, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

Central and South West Corporation, et al. (70-8423)

Central and South West Corporation ("CSW"), a registered holding company, CSW International, Inc. ("CSWI"), and CSW Energy, Inc. ("Energy"), both wholly owned nonutility subsidiary companies of CSW, all at 1616 Woodall Rodgers Freeway, Dallas, Texas 75202, have filed a post-effective amendment under sections 6(a), 7, 9(a), 10, 12(b), and 13(b) of the Act and rules 43, 45, 54, 83, 86, 87, 90 and 91 under the Act to their application-declaration previously filed under sections 6(a), 7, 9(a), 10, 12(b), 13(b), 32 and 33 of the Act and rules 43, 45, 54, 83, 86, 87, 90 and 91 under the Act.

By order dated November 3, 1994 (HCAR No. 26156) ("1994 Order"), CSW was authorized, through December 31, 1997, to (a) organize and invest in CSW de Mexico, S.A. de C.V. ("CSWM"), and CSW de Mexico Servicios ("CSWM Servicios");¹ (b) invest either directly or indirectly, through CSWI, CSWM or other special purpose subsidiaries ("Project Parents"), in exempt wholesale generators ("EWGs") and foreign utility companies ("FUCOs" and, together with EWGs, "Exempt Facilities"); (c) provide directly or indirectly, through CSWI and/or CSWM, certain operational and management services to Exempt Facilities and to foreign electric utility enterprises ("Service Activities" and together with the businesses of the Exempt Facilities, "Permitted Activities"); (d) guarantee, or provide other forms of credit support for, the securities or contractual obligations of CSWI, CSWM and the Project Parents issued or incurred in connection with

the Permitted Activities; and (e) fund such investments from time to time through issuances by CSW, CSWI, CSWM, CSWM Servicios and/or the Project Parents of stock, partnership interests, promissory notes, commercial paper or other debt or equity securities.

The 1994 Order limited the amounts of investment by CSW in subsidiaries engaged in the Permitted Activities and of guaranties or other forms of credit support issued or arranged by CSW on behalf of such subsidiaries (collectively, "Aggregate General Authority") to \$400 million. By order dated September 27, 1995 (HCAR No. 26383) ("1995 Order"), CSW was authorized to increase its authority to make investments under the Aggregate General Authority up to an amount not to exceed 50% of its "consolidated retained earnings," as determined in accordance with rule 53(a)(1).² By order dated January 24, 1997 (HCAR No. 26653) (together with the 1994 Order and the 1995 Order, "Orders"), the Commission authorized CSW to increase its investments in Exempt Facilities in amounts which, when aggregated with the guaranties of the obligations of such entities, would not exceed 100% of CSW's "consolidated retained earnings," as determined in accordance with rule 53(a)(1).

CSW now seeks an extension, through December 31, 2002, of the authority granted in the Orders to (a) invest directly or indirectly in Exempt Facilities, (b) guarantee or provide other forms of credit support for subsidiaries engaged in the ownership and/or operation of Exempt Facilities, (c) fund such investments and/or guaranties through the issuance of securities to third parties, and (d) engage directly or indirectly in Service Activities. In addition, CSWI and Energy seek an extension through December 31, 2002 of authority granted in the 1994 Order and the 1995 Order for CSWI, CSWM, CSWM Servicios and/or the Project Parents to issue equity securities to third parties in connection with the Permitted Activities.

Energy and CSWI also request authority, through December 31, 2002, to (a) acquire the securities of companies ("Intermediate Subsidiaries") that would have direct or indirect ownership interests in companies engaged in Service Activities

¹ Energy was authorized to hold directly one share in CSWM to comply with a requirement of Mexican law that CSWM have a minimum of two shareholders. CSWM was authorized to hold all shares of CSWM Servicios except for one share to be held by CSWI.

² The 1994 Order had also authorized CSWI, CSWM and the Project Parents to issue securities to third parties without recourse to CSW in connection with the Permitted Activities in amounts not to exceed \$600 million in the aggregate. The 1995 Order raised this limit to \$3 billion.

outside the United States ("Foreign Service Companies") and in companies that are organized pursuant to rule 58 under the Act ("Rule 58 Companies") and (b) guarantee or otherwise provide credit support for the securities or contractual obligations of such companies, in amounts not to exceed \$200 million outstanding at any one time. The obligations under the requested guarantees or other forms of credit support would be nonrecourse to CSW.

Further, CSW requests authority for Foreign Service Companies to offer services to those affiliates of such Foreign Service Companies that do not derive, directly or indirectly, any material part of their income from sources within the United States. In accordance with rule 83, compensation for such services would be charged without regard to the restrictions imposed by rule 90(a)(2).

Entergy Power UK plc (70-9081)

Entergy Power UK plc ("EPUK"), Templar House, 81-87 High Holborn, London WC1V 6NU, England, a wholly-owned subsidiary company of Entergy Corporation ("Entergy"), a registered holding company, has filed an application-declaration under sections 6(a), 7, 9(a), 10, 12 (b), (c) and (f) of the Act and rules 45 and 54 thereunder.

EPUK³ proposes to organize an entity ("Issuing Entity") in the form of a special purpose limited partnership ("Limited Partnership") or statutory business trust ("Trust") to issue and sell one or more series of preferred securities ("Entity Interests") in an aggregate principal amount up to \$500 million, from time to time through December 31, 2000.⁴ EPUK will make an equity contribution to the Issuing Entity at the time the Entity Interests are issued. If the Issuing Entity is formed as a Limited Partnership, EPUK or a special purpose corporation wholly-owned by EPUK will acquire all of the general partner interest of the Limited Partnership and act as its general partner. If the Issuing Entity is formed as a Trust, EPUK would acquire all of the Trust's voting interests and the business of the Trust would be conducted by one or more trustees. Holders of the Entity Interests will be either the limited partners of the

Limited Partnership or the holders of preferred interests in the Trust. EPUK represents that its equity contribution to the Issuing Entity will at all times constitute at least 3% of the aggregate equity contributions by all security holders of the Issuing Entity.

In connection with the issuance of Entity Interests, EPUK proposes to issue and sell one or more series of junior subordinated debentures or capital interests (collectively, "Subordinated Securities") to the Issuing Entity. The Issuing Entity will purchase the Subordinated Securities with the proceeds from the sale of its Entity Interests, plus the equity contributions it received from EPUK. Each series of Subordinated Securities will have either a stated maturity date or not stated maturity date, and interest will be paid by EPUK at either a fixed or adjustable rate. The distribution rates, payment dates, redemption, maturity, if any, and other terms of the Subordinated Securities will be substantially similar to those of the Entity Interests, and will be determined by EPUK at the time of issuance pursuant to a subordinated securities agreement ("Subordinated Securities Agreement"). The interest paid by EPUK on the Subordinated Securities will constitute the only source of income for the Issuing Entity to pay monthly, quarterly, or semi-annual distributions on the Entity Interests, as determined at the time of issuance.

Each series of Entity Interests and any corresponding series of Subordinated Securities will be sold at such price and will be entitled to receive such distributions or interest payments on such periodic basis, as determined at the time of sale. No series of Entity Interests or corresponding series of Subordinated Securities will be sold if the interest rate, whether fixed or the initial adjustable rate, would exceed the lower of 15% per annum or market rates at the time of pricing for comparable securities of issuers of comparable credit quality bearing comparable maturities. Interest or distributions calculated in accordance with an adjustable rate will be established by reference to a benchmark rate, such as the London Interbank Offered Rate, the Treasury Rate or orders received in an auction procedure, and will not exceed 15% per annum. Subsequent rate adjustments may be made at established intervals or simultaneously with changes in the benchmark rate.

EPUK may guarantee the payment of distributions on the Entity Interests, payments to the holders of Entity Interests of amounts due upon liquidation of the Issuing Entity or

redemption of the Entity Interests, and certain additional "gross-up" amounts that may be payable in respect of Entity Interests.

EPUK may have the right to defer payment of interest on the Subordinated Securities for specified periods or for an indefinite period so long as dividends are not being paid on, or certain actions are not being taken with respect to the retirement of, the common or preferred stock of EPUK or one or more of the direct or indirect parent companies of EPUK during the period of deferral. The Subordinated Securities would be expressly subordinated to senior indebtedness of EPUK.

Distributions on Entity Interests will be paid periodically, as determined at the time of sale of such series, will be cumulative and will be mandatory to the extent that the Issuing Entity has legally available funds sufficient for such purposes. The availability of funds will depend entirely upon the Issuing Entity's receipt of the amounts paid under the Subordinated Securities. The Issuing Entity may also defer payment of distributions for a specified period or for an indefinite period, but only if and to the extent that EPUK defers interest payments on the Subordinated Securities.

EPUK expects that its interest payments on the Subordinated Securities will be deductible by it for United Kingdom income tax purposes and that the Issuing Entity will not be subject to United States or United Kingdom income tax on the interest received on the Subordinated Securities.

At the option of the Issuing Entity with the consent of EPUK, the Issuing Entity may redeem the Entity Interests, in whole or in part, at a price equal to their stated liquidation preference plus any accrued and unpaid distributions, on or before a date approximately five years after the date of issuance, upon the occurrence of certain adverse tax or regulatory events.⁵ The Entity Interests also may be subject to mandatory redemption under certain circumstances. Moreover, EPUK may reserve the right to exchange the Subordinated Securities for the Entity Interests or to distribute the Subordinated Securities to holders of

⁵ Examples of such adverse events include if the Issuing Entity may become subject to United States or United Kingdom income tax on the interest it received on Subordinated Securities, a determination that the interest payments by EPUK on its Subordinated Securities are not deductible for the United States earnings and profits or United Kingdom income tax purposes, the Issuing Entity becomes subject to a more than minimal amount of other taxes, or if the Issuing Entity becomes subject to regulation as an "investment company" under the Investment Company Act of 1940, as amended.

³ EPUK was incorporated in 1996 as a public limited company under the laws of England to acquire London Electricity plc ("LE"), a foreign utility company ("FUCO"), as defined in section 33 under the Act. EPUK's sole investment and significant asset is the entire share capital of LE.

⁴ The application states that tax considerations will influence whether the Issuing Entity is formed as a Limited Partnership or Trust.

Entity Interests, whereupon the Entity Interests would be canceled.

In the event Subordinated Securities are not treated as indebtedness for United Kingdom income tax purposes or the Issuing Entity is not treated as a partnership or trust, as the case may be, for United States income tax purposes, and the Issuing Entity is required to withhold or deduct certain amounts from payments on the Entity Interests, the Issuing Entity may have the obligation, if the Entity Interests are not redeemed or exchanged, to "gross up" such payments so that the holders of the Entity Interests will receive the same payment after withholding or deduction as they would have received if no withholding or deduction were required.

In the event of liquidation, dissolution or winding up of the Issuing Entity, holders of Entity Interests will be entitled to receive out of assets available for distribution before any distribution of assets to the general partner if the Issuing Entity is a Limited Partnership or to EPUK if the Issuing Entity is a Trust, an amount equal to the stated liquidation preference of the Entity Interests plus any accrued and unpaid distributions.

EPUK states that the constituent documents governing the Issuing Entity will contain provisions limiting the Issuing Entity's activities to (i) the issuance and sale of Entity Interests, (ii) the use of proceeds from the sale of Entity Interests and the equity contributions from EPUK to purchase Subordinated Securities, (iii) the receipt of interest on the Subordinated Securities and (iv) the payment of distributions on the Entity Interests. Moreover, EPUK represents that the constituent documents of the Issuing Entity will not include any interest or distribution coverage or capitalization ratio restrictions on the Issuing Entity's ability to issue and sell additional Entity Interests.⁶ Transfer restrictions will apply to transfers of the general partner interest or voting interests, as the case may be.

EPUK anticipates that the issuance and sale of Entity Interests will be by means of competitive bidding,⁷ or negotiated public offering or private placement with institutional investors. The commission payable to underwriters is not expected to exceed

the lesser of 3.25% of the principal amount of the Entity Interests to be sold or an amount payable for comparable issuances of securities having terms, conditions and features similar to those of the Entity Interests.

EPUK intends to use the net proceeds from the issuance and sale of Entity Interests to repay a portion of the credit facility used to finance the acquisition of LE ("LE Credit Facility").⁸ In connection with such repayment, the LE Credit Facility may be amended and restated, and one or more subsidiaries of Energy formed to hold, with EPUK, LE, may be required to become a guarantor or co-maker of, or jointly or severally obligated to make payments under the amended and restated LE Credit Facility.

Central and South West Corporation, et al. (70-9083)

Central and South West Corporation, a Delaware corporation ("CSW") and a registered holding company under the Act, CSW Energy, Inc., a Texas corporation, and EnerShop, Inc., a Delaware corporation, all located at 1616 Woodall Rodgers Freeway, P.O. Box 660164, Dallas, Texas 75202, and collectively referred to as the "Applicants," have filed a declaration under sections 6(a), 7 and 12(b) of the Act, and rules 45 and 54 thereunder.

Applicants state that under rule 58 of the Act, they intend to acquire the securities of or interests in one or more companies that will engage in all forms of brokering and marketing transactions involving electricity and other energy commodities, including natural gas, oil and coal, at wholesale and retail, through one or more associate energy-related companies (hereinafter referred to as "Marketing Companies"), and to provide incidental related services, such as fuel management, storage and procurement ("Marketing Activities"). In addition, the Applicants from time to time state that they may acquire the securities of or interests in the business of one or more other companies, each of which will engage exclusively in energy-related activities under rule 58 (collectively with Marketing Companies, "Energy-Related Companies").

In connection with the activities of the Energy-Related Companies, the Applicants seek authority to issue or arrange various kinds of credit support in an aggregate amount that will not exceed \$250 million, as required or

appropriate for any Energy-Related Company, directly or indirectly: (i) to secure debt financing; (ii) to satisfy bid bond requirements; and/or (iii) to satisfy credit support requirements in connection with exempt activities conducted by Energy-Related Companies and/or financing documents and agreements to which any Energy-Related Company (directly or indirectly) becomes a party ("Guarantees"). The Applicants state that any Guarantee issued by them on behalf of any Energy-Related Company will be included in the determination of aggregate investment for purposes of rule 58.

The debt financing guaranteed by the Applicants will not: (i) exceed a term of fifteen years; or (ii)(a) bear a rate equivalent to a floating interest rate in excess of 2% over the prime rate, London Interbank Offered Rate or other appropriate index, in effect from time to time, or (b) bear a fixed rate in excess of 2.5% above the yield at the time of issuance of United States Treasury obligations of a comparable maturity. Any commitment or other fees with respect to the debt will not exceed one percent per annum of the total amount of debt financing.

The Applicants state that the Energy-Related Companies will take appropriate measures in the normal course of their business to mitigate the risks associated with electric power and fuel purchase or sale contracts. CSW will not seek recovery through higher rates to customers of its operating utility company subsidiaries to compensate CSW for any possible losses that it may sustain in connection with Guarantees or its investment in Energy-Related Companies.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 97-21594 Filed 8-14-97; 8:45 am]

BILLING CODE 8010-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-38911; File No. SR-DCC-97-08]

Self-Regulatory Organizations; Delta Clearing Corp.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to the Amendment of Fees Charged for Options

August 8, 1997.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934

⁶In EPUK's view, such restrictions would not be necessary because the interest payments by EPUK on the Subordinated Securities will be sufficient to fully service the distributions on Entity Interests.

⁷The price for Entity Interests to be sold through the competitive bidding process is expected to range from 95% to 105% of the liquidation amount of that particular series of Entity Interests.

⁸EPUK states that neither the proceeds from the issuance and sale of Entity Interests nor any savings derived from the repayment of the LE Credit Facility will be used to make new investments in an exempt wholesale generator, as defined in section 32 of the Act, or any other FUCO.

("Act"),¹ notice is hereby given that on July 30, 1997, 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 amend DCC's fee schedule for the clearance of options on U.S. Government securities.

II. Self-Regulatory Organization's Statement for 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 statutory basis for the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. DCC had 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

Currently, DCC charges each party to an options contract submitted to DCC for settlement a fee based on the maturity date of the option. Each participant pays five dollars for options that mature within fourteen days, ten dollars for options that mature within fifteen to ninety days, and fifteen dollars for options that mature within ninety-one days to two years.

The proposed rule change amends DCC's fee schedule for the clearance of options. Each participant will pay a fee of three dollars for options that mature within thirty-three days, four dollars for options that mature within thirty-four to sixty-three days, five dollars for options that mature within sixty-four to 123 days, and seven dollars for options that mature within 124 days to two years. In addition, participants will be charged all out of pocket charges including but not limited to charges by Federal Reserve banks for delivery of securities and money through FedWire and any charges by DCC's clearing bank.

DCC believes that the proposed rule change is consistent with Section 17A(b)(3)(D) of the Act,³ which requires that the rules of a registered clearing agency provide for equitable allocation of reasonable dues, fees, and other charges for services which it provides to its participants. DCC believes that the proposed rule change will result in increased utilization of its clearing services thereby resulting in more securities transactions being cleared and settled through a registered clearing agency environment.

(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

Because the foregoing rule change establishes or changes a due, fee, or other charge imposed by DCC, it has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act⁴ and Rule 19b-4(e)(2) thereunder.⁵ 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 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, N.W., Washington, D.C. 20549. Copies of such filing will also be available for inspection and copying at DCC. All submissions should refer to the File No. SR-DCC-97-08 and should be submitted by September 5, 1997.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.⁶

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 97-21682 Filed 8-14-97; 8:45 am]

BILLING CODE 8010-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-38912; File No. SR-PCX-97-23]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Pacific Exchange, Inc. ("PCX") Relating to Revision of Membership Definitions in the PCX Constitution and Clarifying Constitutional Transfer Language

August 8, 1997.

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 July 23, 1997, the Pacific Exchange Inc. ("PCX" or "Exchange") 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 Exchange. 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 Exchange is proposing to amend Articles V and VII of the Constitution to reflect a Board and member vote to revise certain membership definitions in the Constitution and to clarify the Transfer of Membership Article in the Constitution. The text of the proposed rule change is below. Additions are italicized; deletions are bracketed.

¹ 15 U.S.C. 78s(b)(1).

² The Commission has modified parts of these statements.

³ 15 U.S.C. 78q-1(b)(3)(D).

⁴ 15 U.S.C. 78s(b)(3)(A)(ii).

⁵ 17 CFR 240.19b(e)(2).

⁶ 17 CFR 200.30-3 (a)(12).

¹ 15 U.S.C. § 78s(b)(1) (1988).

² 17 CFR 240.19b-4 (1991).

Article V—Membership in the Exchange

¶ 1351 Number of Memberships

Sec. 1. No change.

¶ 1356 Privileges

Sec. 2. No change.

¶ 1361 Definition of “Member”

Sec. 3. The term “member” as used throughout the Constitution and Rules of the Exchange shall *refer to* [mean] the natural person in whose name the membership is held and who is in good standing. [An “inactive” member shall refer to a natural person who owns or inherits a membership which they intend to keep for the sole purpose of acting as a lessor.]

¶ 1366 Definition of “Member Firm”

Sec. 4. The term “member firm” as used throughout the Constitution and Rules of the Exchange shall *refer to* [mean] a partnership, corporation, *limited liability company* or other organization in good standing *who owns or leases a membership or upon whom* [which] a member has conferred privileges of [his] membership pursuant to and in compliance with Article VIII of this Constitution.

¶ 1369 Definition of “Member Organization”

Sec. 5. The term “member organization” as used throughout the Constitution and Rules of the Exchange shall *refer to* [mean] a sole proprietor, partnership, corporation, *limited liability company* or other organization in good standing *who owns or leases a membership or upon whom* [which] a member has conferred privileges of membership pursuant to and in compliance with Article VIII of this Constitution.

¶ 1371 Definition of “Allied Member”

Sec. 6. The term “allied member” as used throughout the Constitution and Rules of the Exchange shall *refer to* a non-member, who is:

[(I) A general partner in a member firm; or]

(1) [(ii)] An employee of a member firm who controls such member firm, or [who is either:

(a) A director of such corporation; or

(b) A principal executive officer of such corporation.]

(2) *An employee of a member firm corporation who is a director or a principal executive officer of such corporation, or*

(3) *An employee of a member firm limited liability company who is a manager or a principal executive officer of such limited liability company, or*

(4) *A general partner in a member firm partnership;*

and who has been approved by the Exchange as an allied member.

¶ 1376 Definition of “Associated Person”

Sec. 7. The term “associated person” as used throughout the Constitution and Rules of the Exchange shall *refer to* a [means any] person who is a partner, officer, director, member of a Limited Liability Company, trustee of a Business Trust, [or] employee of a member organization or any person directly or indirectly controlling, controlled by or under common control with a member organization.

¶ 1381 Definition of “Floor Member” [“Control”]

Sec. 8. The term “*floor member*” [“control”] as used throughout the [in this] Constitution and Rules of the Exchange shall *refer to* an individual, approved as a member of the Exchange, who meets the qualification requirements for the purpose of exercising full trading privileges on a floor of the Exchange on behalf of a member organization [be defined in the Rules of the Board of Governors of the Exchange].

¶ 1382 Definition of “Inactive Lessor”

Sec. 9. The term “inactive lessor” as used throughout the Constitution and Rules of the Exchange shall *refer to* a natural person, firm or other such entity as the Board may approve, who owns or inherits a membership for the sole purpose of acting as a lessor.

¶ 1383 Definition of “Non-Resident Member Organization”

Sec. 10. The term “non-resident member organization” as used throughout the Constitution and Rules of the Exchange shall *refer to*:

(1) *In the case of an individual, one who resides in or has their principal place of business in any place not subject to the jurisdiction of the United States;*

(2) *In the case of a corporation, one incorporated in or having its principal place of business in any place not subject to the jurisdiction of the United States;*

(3) *In the case of a partnership or other unincorporated organization or association, one having its principal place of business in any place not subject to the jurisdiction of the United States.*

* * * * *

Article VII—Transfer of Membership

¶ 1451 Transfer

Sec. 1. *Transfer of Membership in the Exchange must comply with the provisions of Article VII* [may be transferred by a member only in accordance with the provisions of this Article VII and only to a person whose application and election becomes effective under Article VI].

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 Exchange 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 Exchange 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

Purpose

The purpose of the proposed rule change to Article V is to revise certain membership-related definitions in the Constitution. These proposed revisions are the result of several PCX Board approvals and member votes. Last year, the membership approved a comprehensive revision to Rule 1 of the Board of Governors, placing all of the relevant provisions relating to membership at the Exchange in a central location in the PCX rules. This included moving any membership-related definitions from various sections of the Constitution and placing them, complete with revisions, all into Rule 1 with the other provisions relating to membership. Prior to the actual proposed rule filing to remove and revise these Constitutional definitions, some members expressed concerns that these definitions should remain in the Constitution so that any changes would have to be effected by a member vote. Therefore, the Board approved the reinstatement of the revised definitions back into the Constitution and the members agreed. This proposed rule change revises the various sections of Article V of the Constitution to reflect the revised definitions agreed upon pursuant to the member votes and the Board approvals.

The purpose of the proposed change to Article VII, Section 1, is to clarify the

language of the Article to clearly state that transfers of memberships needed to be made pursuant to this Constitutional Article. When the new Rule 1 was being revised, the Board and membership agreed to change the language of Section 1, Article VII. The proposed change was viewed as somewhat confusing by the membership. Consequently, after Board approval and member vote, the Exchange is now proposing to change Article VII so that it clearly states that transfers of membership must comply with the provisions of Article VII in the Constitution.

Basis

Pursuant to Rule 19b-4(e)(3), the proposed rule change is concerned solely with the administration of the Exchange. The proposed rule change is consistent with Section 6(b) of the Act, in general, and Section 6(b)(5), in particular, in that it is designed to promote just and equitable principles of trade because the definitions, reflecting the changes desired by the membership, will be consistent throughout the PCX Constitution and Rules and a membership vote will be necessary to approve any changes to these definitions.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange 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

Written comments on the proposed rule change were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has designated this proposal as concerned solely with the administration of the Exchange under Section 19(b)(3)(A)(iii) of the Act³ and subparagraph (e)(3) of Rule 19b-4,⁴ which renders the proposed rule change effective on July 23, 1997, the date of receipt of this filing by the Commission.

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. People 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 the filing will also be available for inspection and copying at the PCX's principal offices. All submissions should refer to File No. SR-PCX-97-23 and should be submitted by September 5, 1997.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.⁵

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 97-21593 Filed 8-14-97; 8:45 am]

BILLING CODE 8010-01-M

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #2970]

State of Idaho; (Amendment #1)

In accordance with a notice from the Federal Emergency Management Agency dated July 25, 1997, the above-numbered Declaration is hereby amended to include Madison County, Idaho as a disaster area due to damages caused by severe storms, snowmelt, land and mud slides, and flooding which occurred March 14 through June 30, 1997.

In addition, applications for economic injury loans from small businesses located in the contiguous county of Teton in the State of Idaho may be filed until the specified date at the previously designated location.

All other information remains the same, i.e., the deadline for filing applications for physical damage is September 22, 1997, and for economic

injury the termination date is April 22, 1998.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Dated: August 8, 1997.

Becky C. Brantley,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 97-21686 Filed 8-14-97; 8:45 am]

BILLING CODE 8025-01-P

SMALL BUSINESS ADMINISTRATION

[Declaration of Economic Injury Disaster #9577]

State of Tennessee; (and Contiguous Counties in North Carolina)

Cocke County and the contiguous Counties of Greene, Hamblen, Jefferson, and Sevier in the State of Tennessee, and Haywood, Madison, and Swain Counties in the State of North Carolina constitute an economic injury disaster loan area as a result of a rockslide that occurred on July 1, 1997, on the North Carolina side of Interstate 40 and closed it to all east and west traffic. Eligible small businesses and small agricultural cooperatives without credit available elsewhere may file applications for economic injury assistance for this disaster until the close of business on May 6, 1998, at the address listed below or other locally announced locations:

U.S. Small Business Administration,
Disaster Area 2 Office, One Baltimore
Place, Suite 300, Atlanta, GA 30308

The interest rate for eligible small businesses and small agricultural cooperatives is 4 percent.

The economic injury number for North Carolina is 957800.

(Catalog of Federal Domestic Assistance Program No. 59002.)

Dated: August 6, 1997.

Ginger Lew,

Acting Administrator.

[FR Doc. 97-21687 Filed 8-14-97; 8:45 am]

BILLING CODE 8025-01-P

DEPARTMENT OF STATE

[Public Notice #2579]

Bureau of Political-Military Affairs; Determination Under the Foreign Assistance Act of 1961

Pursuant to Section 654(c) of the Foreign Assistance Act of 1961, as amended ("the Act"), notice is hereby given that the Acting Secretary of State has made a determination pursuant to the Foreign Operations, Export Financing and Related Programs

³ 15 U.S.C. § 78s(b)(3)(A)(iii).

⁴ 17 CFR 240.19b-4(e)(3).

⁵ 17 CFR 200.30-3(a)(12).

Appropriations Act, 1994, the Foreign Operations, Export Financing and Relating Programs Appropriations Act, 1995, and the Foreign Operations, Export Financing and Related Programs Appropriations Act, 1996, and has concluded that publication of the determination would be harmful to the national security of the United States.

Dated: July 31, 1997.

Thomas E. McNamara,

Assistant Secretary of State for Political-Military Affairs.

[FR Doc. 97-21636 Filed 8-14-97; 8:45 am]

BILLING CODE 4710-25-M

DEPARTMENT OF STATE

[Public Notice # 2578]

Advisory Committee on International Communications and Information Policy; Public Meeting

The Department of State is holding the next meeting of its Advisory Committee on International Communications and Information Policy. The Committee was renewed in 1996, in order to continue to provide a formal channel for regular consultation and coordination on major economic, social and legal issues and problems in international communications and information policy, especially as these issues and problems involve users of information and communication services, providers of such services, technology research and development, foreign industrial and regulatory policy, the activities of international organizations with regard to communications and information, and developing country interests.

The 30-person committee was appointed by Ambassador Vonya B. McCann, United States Coordinator for International Communications and Information Policy, U.S. Department of State, and serves under the Chairmanship of Ed Black, President, Computer & Communications Industry Association.

The purpose of this meeting will be to hear reports from the working groups on various issues that chart the future direction and work plan of the committee. The members will look at the substantive issues on which the committee should focus, as well as specific countries and regions of interest to the committee.

This meeting will be held on Thursday, September 4, 1997, from 9:30 a.m.-12:30 p.m. in Room 1107 of the Main Building of the U.S. Department of State, located at 2201 "C" Street, N.W., Washington, D.C. 20520. Members of

the public may attend these meetings up to the seating capacity of the room. While the meeting is open to the public, admittance to the State Department Building is only by means of a pre-arranged clearance list. In order to be placed on the preclearance list, please provide your name, title, company, social security number, date of birth, and citizenship to Shirlett Brewer at (202) 647-5233 or by fax at (202) 647-5957. All attendees must use the "C" Street entrance. One of the following valid ID's will be required for admittance: any U.S. driver's license with photo, a passport, or a U.S. Government agency ID.

For further information, contact Timothy C. Finton, Executive Secretary of the Committee, at (202) 647-5385.

Dated: August 1, 1997.

Timothy C. Finton,

Executive Secretary, Advisory Committee for International Communications and Information Policy.

[FR Doc. 97-21634 Filed 8-14-97; 8:45 am]

BILLING CODE 4710-45-M

DEPARTMENT OF TRANSPORTATION

Aviation Proceedings, Agreements Filed During the Week of August 8, 1997

The following Agreements were filed with the Department of Transportation under the provisions of 49 U.S.C 412 and 414. Answers may be filed within 21 days of date of filing.

Docket Number: OST-97-2780

Date Filed: August 4, 1997

Parties: Members of the International Air Transport Association

Subject: COMP Telex Mail Vote 886, Fares from South Africa, *Intended effective date:* September 1, 1997

Docket Number: OST-97-2781

Date Filed: August 4, 1997

Parties: Members of the International Air Transport Association

Subject: PTC12 Telex Mail Vote 885, Reso 010w—Seasonal Periods for, South Atlantic-Europe/Mideast fares, TW684—Amendment to Mail Vote, TW686—Amendment to Mail Vote, *Intended effective date:* September 1, 1997

Docket Number: OST-97-2782

Date Filed: August 4, 1997

Parties: Members of the International Air Transport Association

Subject: PTC12 USA-EUR 0031 dated July 14, 1997, USA-Austria/Belgium/Germany/Netherlands/Scandinavia/Switzerland Resolutions, Minutes—PTC12 USA-EUR 0032 dated July 18, 1997, r-1, 005k r-8—090nn, r-14—

077oo, r-20—077yy, r-2—001a, r-9—210ss, r-15—088dd, r-21—078pp, r-3—002, r-10—072cc, r-16—092x, r-22—078uu, r-4—006ss, r-11—073a, r-17—071ss, r-23—078ww, r-5—044vv, r-12—073dd, r-18—072zz, r-24—092aa, r-6—054vv, r-13—075bb, r-19—075ee, r-7—064vv,

Intended effective date: October 1, 1997

Paulette V. Twine,

Chief, Documentary Services.

[FR Doc. 97-21591 Filed 8-14-97; 8:45 am]

BILLING CODE 4910-62-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Department of Transportation, Federal Aviation Administration (DOT/FAA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Act (44 U.S.C. 3501 *et seq.*) this notice announces that the information collection request described below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The FAA issued a final rule on Commercial Passenger-Carrying Operations in Single Engine Aircraft under Instrument Flight Rules on July 31, 1997. This notice describes the paperwork burden associated with that rule and allows for a 60-day comment period while the paperwork package is being reviewed by OMB. The following information describes the nature of the information collection and its expected burden.

With respect to the following collection of information, FAA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FAA's functions, including whether the information will have practical utility; (2) 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) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, 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.

DATES: Submit any comments to OMB and FAA by October 14, 1997.

SUPPLEMENTARY INFORMATION:

Title: Commercial Passenger-Carrying Operations in Single Engine Aircraft under Instrument Flight Rules.

Need: The information collection associated with Part 135 is necessary to ensure the continued airworthiness of the affected single engine aircraft used in air transportation. The recordkeeping requirements reflect the continued airworthiness of the affected operators, inasmuch as these amendments required maintenance for the newly-required, redundant electrical and vacuum systems.

Respondents: 1800 operators.

Frequency: (Recordkeeping) Approximately five times annually for engine trend monitoring recordkeeping, i.e., oil analysis processing and recordkeeping; one time recording of the maintenance procedures required for the redundant electrical and vacuum systems.

Burden: The FAA conservatively estimates that, on average, the rule would require six additional work hours per year during the first year for each of the approximately 1800 affected carriers, for an estimated 10,800 on-demand operators potentially affected by this rule. However, the FAA does not know how many operators will take the necessary steps to comply with the regulation and gain the benefits of so doing. Therefore, the FAA considers this estimate to be overstated, and seeks comments on this estimate.

For Further Information: or to obtain a copy of the request for clearance submitted to OMB, you may contact Ms. Judy Street at the Federal Aviation Administration, Corporate Information Division, ABC-100, 800 Independence Avenue, SW., Washington, DC 20591.

Comments may be submitted to the FAA at the address above and to Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10202, Attention FAA Desk Officer, 725 17th Street, NW., Washington, DC 20503.

Issued in Washington, DC, on August 8, 1997.

Steve Hopkins,

Manager, Corporate Information Division, ABC-100.

[FR Doc. 97-21590 Filed 8-14-97; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Availability of Draft Environmental Impact Statement (EIS), Notice of Public Comment Period and Schedule of Public Hearings

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of availability, notice of comment period, notice of public hearings.

SUMMARY: In accordance with requirements of the National Environmental Policy Act of 1969, as amended, (NEPA), 42 U.S.C. 4332(2)(C), the FAA is preparing an Environmental Impact Statement (EIS) for Terminal Doppler Weather Radar (TDWR) to serve John F. Kennedy International and LaGuardia Airports, New York, New York. A Draft EIS document has been prepared and is available for public review and comment. Written request for the Draft EIS and written comments for the Draft EIS can be submitted as follows: Federal Aviation Administration, Office of the Chief Counsel, Attention: Docket No. 28365, 800 Independence Avenue, Washington, DC 20591. Public hearings will be held on September 17 and 18, 1997. The public comment period will commence August 22, 1997 and will close on October 10, 1997.

DATES: The start of the comment period on Draft EIS will be concurrent with the **Federal Register** notice of availability as filed by the Environmental Protection Agency. The comment period will start on August 22, 1997 and will end on October 10, 1997. Public hearings on the Draft EIS will be held on Wednesday evening September 17, Thursday afternoon September 18, and Thursday evening September 18. On Wednesday evening September 17, 1997, information exhibits will open at 6:30 p.m., and presentations and comments will start at 7:00 p.m. On Thursday afternoon September 18, 1997, exhibits will open at 12:30 p.m. and presentation and public comments will begin at 1:00 p.m., and on Thursday evening October 18, 1997, exhibits will open at 6:30 and the presentation and comments will begin at 7:00 p.m.

ADDRESSES: Locations for the public hearings are as follows: Wednesday evening, September 17, 1997, 6:30 p.m., The Bach Club, Ocean Room, 129 Beach 116th Street, Rockaway Park, NY 11694. Thursday afternoon September 18, 1997, 12:30 p.m., The Playhouse Theater,

Kingsborough Community College, The City University of New York, 2001 Oriental Boulevard, Brooklyn, NY 11235. Thursday evening September 18, 1997, 6:30 p.m., The Mill Basin School, PS 236, 6302 Avenue U, Brooklyn, NY 11234.

Written requests for the Draft EIS and written comments on the Draft EIS should be submitted to the FAA as follows: Federal Aviation Administration, Attention: Office of the Chief Counsel, AGC-200, Docket No. 28365, 800 Independence Avenue, Washington, DC 20591.

FOR FURTHER INFORMATION CONTACT:

Jerome D. Schwartz, Environmental Specialist, Federal Aviation Administration, Wind Shear and Weather Radar Products Team, AND-420, 800 Independence Avenue, SW, Washington, DC 20591, telephone (202) 267-9841.

SUPPLEMENTARY INFORMATION: In accordance with requirements of the National Environmental Policy Act of 1969, as amended, (NEPA), 42 U.S.C. 4332(2)(C), the FAA is preparing an Environmental Impact Statement (EIS). The Draft EIS analyzes potential impacts from the installation of the proposed Terminal Doppler Weather Radar (TDWR) and alternative technologies. Public hearings on the Draft EIS will be held the evenings of September 17 and 18, and the afternoon of September 18, 1997. For meeting details see above **DATES** and **ADDRESSES** sections.

Comments from interested parties on the Draft EIS are encouraged and may be presented verbally at a public hearing or may be submitted in writing to the FAA at Federal Aviation Administration, Attention: Office of Chief Counsel, ACG-200, Docket 28365, 800 Independence Avenue, SW, Washington, DC 20591. The public comment period will close on Friday October 10, 1997.

Sign interpretation will be available if requested at least five calendar days before the meetings at which it is requested.

Issued in Washington, DC on August 12, 1997.

Daniel P. Salvano,

Acting Director, Communications, Navigation, and Surveillance Systems, AND-1.

[FR Doc. 97-21662 Filed 8-14-97; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration**

[Summary Notice No. PE-97-42]

Petitions for Exemption; Summary of Petitions Received; Dispositions of Petitions Issued**AGENCY:** Federal Aviation Administration (FAA), DOT.**ACTION:** Notice of petitions for exemption received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption (14 CFR part 11), this notice contains a summary of certain petitions seeking relief from specified requirements of the Federal Aviation Regulations (14 CFR Ch. I), dispositions of certain petitions previously received, and corrections. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before September 4, 1997.

ADDRESSES: Send comments on any petition in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attn: Rule Docket (AGC-200), Petition Docket No. _____, 800 Independence Avenue, SW., Washington, DC 20591.

Comments may also be sent electronically to the following internet address: 9-NPRM-CMNTS@faa.dot.gov.

The petition, any comments received, and a copy of any final disposition are filed in the assigned regulatory docket and are available for examination in the Rules Docket (AGC-200), Room 915G, FAA Headquarters Building (FOB 10A), 800 Independence Avenue, SW., Washington, D.C. 20591; telephone (202) 267-3132.

FOR FURTHER INFORMATION CONTACT:

Heather Thorson (202) 267-7470 or Angela Anderson (202) 267-9681 Office of Rulemaking (ARM-1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to paragraphs (c), (e), and (g) of § 11.27 of Part II of the Federal Aviation Regulations (14 CFR part 11).

Issued in Washington, DC, on August 11, 1997.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

Petitions for Exemption*Docket No.:* 28952.*Petitioner:* Minebea Technologies PTE Ltd.*Sections of the FAR Affected:* 14 CFR 119.5(h).

Description of Relief Sought: To permit Minebea Technologies PIT Ltd., the holder of a 14 CFR part 125 operating certificate authorizing noncommon or private carriage to and from the United States, to operate its McDonnell Douglas DC-10 aircraft outside the United States under a cargo wet lease agreement with Thai Airways.

Docket No.: 26490.*Petitioner:* Delta Air Lines, Inc.*Sections of the FAR Affected:* 14 CFR 121.310(m).

Description of Relief Sought: To permit Delta Air Lines to operate certain Lockheed L-1011-385-3 aircraft that have more than a 60-foot distance between emergency exits.

Docket No.: 28974.*Petitioner:* The Ask First Society.*Sections of the FAR Affected:* 14 CFR 91.319(a) (1) and (2).

Description of Relief Sought: To permit The Ask First Society to conduct pilot and flight instructor training in experimental gyroplanes for compensation or hire.

Dispositions of Petitions*Docket No.:* 26302.*Petitioner:* FlightSafety International.

Sections of the FAR Affected: 14 CFR 135.293; 135.297; 135.299; 135.377 (a) (2) and (3), and (b)(2); 135.339 (a)(2), (b), and (c); and appendix H to part 121.

Description of Relief Sought/Disposition: To permit FlightSafety International (FSI) to use its qualified instructor pilots or pilot check airmen in approved simulators to train and check the pilot of part 135 certificate holders that contract with FSI for training. *Grant, 7/29/97, Exemption No. 5241G.*

Docket No.: 26067.*Petitioner:* SimuFlite Training International.

Sections of the FAR Affected: 14 CFR 135.293; 135.297; 135.299; 135.337 (a) (2) and (3), and (b)(2); 135.339 (a) (2), (b), and (c); and appendix H to part 121.

Description of Relief Sought/Disposition: To permit SimuFlite to use its qualified instructor pilots or pilot check airmen in approved simulators to train and check pilots of part 135 certificate holders that contract with

SimuFlite for training. *Grant, 7/29/97, Exemption No. 5187E.*

Docket No.: 28846.*Petitioner:* SouthCentral Air.*Sections of the FAR Affected:* 14 CFR 121.359(g).

Description of Relief Sought/Disposition: To permit SouthCentral to operate certain Beechcraft 1900C aircraft with oxygen masks that are not equipped with installed microphones. *Grant, 7/29/97, Exemption No. 6596C.*

Docket No.: 24541.*Petitioner:* Boeing Commercial Airplane Group.*Sections of the FAR Affected:* 14 CFR 91.611.

Description of Relief Sought/Disposition: To permit Boeing to conduct ferry flights with one engine inoperative on its Boeing 707, 720, 727, and 747 aircraft without obtaining a special ferry permit. *Grant, 7/29/97, Exemption No. 4467F.*

Docket No.: 26721.*Petitioner:* Regional Airline Association.

Sections of the FAR Affected: 14 CFR 135.63(a)(4) and subparts E, G, and H of part 135.

Description of Relief Sought/Disposition: To permit Regional Airline Association-member airlines and other similarly situated air carriers to train, check, and qualify flight crewmembers in accordance with 14 CFR 121.681 and 121.683; subparts N and O of part 121; and appendixes E, F, and H to part 121. *Grant, 7/29/97, Exemption No. 5450C.*

Docket No.: 28781.*Petitioner:* United Airlines, Inc.*Sections of the FAR Affected:* 14 CFR 121.438(a)(1).

Description of Relief Sought/Disposition: To permit United Airlines, Inc., to allow time as second-in-command (SIC) pilots that have fewer than 100 hours of flight time as SIC in part 121 operations in the type of airplanes being flown to perform takeoffs and landings at airports designated as special airports. *Denial, 7/24/97, Exemption No. 6662.*

[FR Doc. 97-21726 Filed 8-14-97; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION**Federal Highway Administration****Environmental Impact Statement: Johnston, Rhode Island****AGENCY:** Federal Highway Administration (FHWA), RIDOT.**ACTION:** Notice of Intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an Environmental Impact Statement will be prepared for the development of Improved Highway Access to the Environmental Management District of Western Johnston and Cranston.

FOR FURTHER INFORMATION CONTACT:

Dan Berman, Assistant Division Administrator, Federal Highway Administration, 380 Westminster Mall, Room 547, Providence, RI, 02903, Telephone: (401) 528-4560. OR Edmund T. Parker, Jr., P.E., Chief Design Engineer, Rhode Island Department of Transportation, 2 Capitol Hill, Room 231-D, Providence, RI, 02903, Telephone: (401) 277-4911.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the Rhode Island Department of Transportation (RIDOT) and the Rhode Island Resource Recovery Corporation (RIRRC), will prepare the Environmental Impact Statement (EIS) for the development of Improved Highway Access to the Environmental Management District of Western Johnston and Cranston.

This EIS will investigate scientific and engineering studies and other activities necessary to determine the environmental and socioeconomic impacts of various alternative routing scenarios to improve the highway access to the Environmental Management District.

Improved highway access is deemed necessary because of the high volume of heavy truck traffic generated daily by the industries located there. There are currently between 1,200 and 1,500 one-way trips into the District by heavy trucking to serve the Central Landfill and the Materials Recycling Facility, both of which are operated by the Rhode Island Resource Recovery Corporation, nine private waste management firms, and a number of heavy industry waste management satellite firms, all of which are located in the Environmental Management District.

It is expected that the daily volume of heavy trucking into and out of the District will expand appreciably and steadily into the foreseeable future. Most of the truck traffic is currently utilizing Rhode Island Route 14 (Plainfield Pike), which is also rapidly developing as a commercial artery. The objective of this project is to determine the best route, if any, alternative to the existing principal access now provided by Plainfield Pike. This would accommodate the increasing volume of heavy trucking safely and efficiently and eliminate or minimize the negative impacts of such heavy industrial trucking on the commercial and retail

development potential of Plainfield Pike.

A cursory review of the project area and existing roadways was performed using the 1996 Aerial Topographic Mapping provided by the RIRRC, and USGS Quadrangle Maps. This review identified three (3) different options for an improved access roadway to the site with enough merit to be considered for further evaluations. The following paragraphs give a brief discussion of each option.

Option No. 1—No Build/Green Hill Avenue and Shun Pike

This option would consist of maintaining the current infrastructure as it is today. The industrial park site currently can be accessed by commercial vehicles from Plainfield Pike (Rte 14) via Green Hill Road and Shun Pike. Both of these roadways do not have the structural capacity to support the proposed traffic volumes from the industrial park at build-out. Therefore, Green Hill Avenue, a section of Shun Pike from Green Hill Avenue to the proposed industrial park, and the access roadway would be maintained as two (2) twelve foot (12') travel lanes with paved shoulders and would be structurally upgraded from their present capacity.

Option No. 2—New Access Roadway From Comstock Parkway to Site

This option would consist of constructing a roadway on new location from the intersection of the Plainfield Pike and Comstock Parkway in a northerly direction to the industrial park site. The roadway would travel somewhat parallel to the Simmons Lower Reservoir, then cross between the Simmons Upper and Lower Reservoirs at an existing earthen causeway and then turn north to Shun Pike.

Option No. 3—New Diamond Interchange at I-295 and Scituate Avenue

This option would consist of constructing new I-295 northbound "on" and "off" ramps and new I-295 southbound "on" and "off" ramps at the existing Scituate Avenue overpass to create a new "Diamond" style interchange. Also, Scituate Avenue will be reconstructed from the interchange to the site; and on the easterly side of the interchange, Scituate Avenue would be broken into two (2) segments by installing two (2) new cul-de-sacs. Finally, a section of Shun Pike would be reconstructed to provide better access to the Central Landfill.

A scoping meeting to discuss the environmental impacts will be held on

Wednesday September 15, 1997, from 9:00 am to 12:00 am, in the Rhode Island Resource Recovery Corporation Board Room. Written comments received will be incorporated into this NEPA scoping process.

In addition, a public hearing will be held in June 1998 to receive verbal comments regarding the Environmental Impact Statement. Public notice will be given of the time and place of the public hearing. The draft EIS will be available for public and agency review and comment prior to the public hearing.

To provide that a full range of issues related to this proposed action are addressed and all significant issues are identified, comments and suggestions regarding this scoping session are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be directed to the Rhode Island Department of Transportation at the above address.

Dan Berman,

Assistant Division Administrator, Federal Highway Administration.

[FR Doc. 97-21644 Filed 8-14-97; 8:45 am]

BILLING CODE 4910-22-M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. 97-052; Notice 1]

Notice of Receipt of Petition for Decision That Nonconforming 1996-1997 Ducati 748 Biposto Motorcycles Are Eligible for Importation

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice of receipt of petition for decision that nonconforming 1996-1997 Ducati 748 Biposto motorcycles are eligible for importation.

SUMMARY: This document announces receipt by the National Highway Traffic Safety Administration (NHTSA) of a petition for a decision that 1996-1997 Ducati 748 Biposto motorcycles that were not originally manufactured to comply with all applicable Federal motor vehicle safety standards are eligible for importation into the United States because (1) they are substantially similar to vehicles that were originally manufactured for importation into and sale in the United States and that were certified by their manufacturer as complying with the safety standards, and (2) they are capable of being readily altered to conform to the standards.

DATES: The closing date for comments on the petition is September 15, 1997.

ADDRESSES: Comments should refer to the docket number and notice number, and be submitted to: Docket Section, Room 5109, National Highway Traffic Safety Administration, 400 Seventh St., SW, Washington, DC 20590. (Docket hours are from 9:30 a.m. to 4 p.m.)

FOR FURTHER INFORMATION CONTACT: George Entwistle, Office of Vehicle Safety Compliance, NHTSA (202-366-5306).

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 30141(a)(1)(A), a motor vehicle that was not originally manufactured to conform to all applicable Federal motor vehicle safety standards shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under 49 U.S.C. 30115, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this decision in the **Federal Register**.

Champagne Imports, Inc. of Lansdale, Pennsylvania ("Champagne") (Registered Importer 90-009) has petitioned NHTSA to decide whether 1996-1997 Ducati 748 Biposto motorcycles are eligible for importation into the United States. The vehicles which Champagne believes are substantially similar are 1996-1997 Ducati 916 motorcycles that were manufactured for importation into, and sale in, the United States and certified by their manufacturer as conforming to all applicable Federal motor vehicle safety standards.

The petitioner claims that it carefully compared non-U.S. certified 1996-1997 Ducati 748 Biposto motorcycles to their U.S. certified counterparts, and found the vehicles to be substantially similar with respect to compliance with most Federal motor vehicle safety standards.

Champagne submitted information with its petition intended to demonstrate that non-U.S. certified 1996-1997 Ducati 748 Biposto motorcycles, as originally manufactured, conform to many Federal motor vehicle safety standards in the same manner as their U.S. certified counterparts, or are capable of being readily altered to conform to those standards.

Specifically, the petitioner claims that non-U.S. certified 1996-1997 Ducati 748 Biposto motorcycles are identical to their U.S. certified counterparts with respect to compliance with Standard Nos. 106 *Brake Hoses*, 111 *Rearview Mirrors*, 116 *Brake Fluid*, 119 *New Pneumatic Tires for Vehicles other than Passenger Cars*, and 122 *Motorcycle Brake Systems*.

Petitioner also contends that the vehicles are capable of being readily altered to meet the following standards, in the manner indicated:

Standard No. 108 *Lamps, Reflective Devices and Associated Equipment*: Installation of U.S.-model headlamp assemblies.

Standard No. 120 *Tire Selection and Rims for Vehicles other than Passenger Cars*: Installation of a tire information placard.

Standard No. 123 *Motorcycle Controls and Displays*: Installation of a U.S. model speedometer calibrated in miles per hour.

The petitioner also states that vehicle identification number plates meeting the requirements of 49 CFR part 565 will be affixed to non-U.S. certified 1996-1997 Ducati 748 Biposto motorcycles.

Comments should refer to the docket number and be submitted to: Docket Section, National Highway Traffic Safety Administration, Room 5109, 400 Seventh Street, SW., Washington, DC 20590. It is requested but not required that 10 copies be submitted.

All comments received before the close of business on the closing date indicated above will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition will be published in the **Federal Register** pursuant to the authority indicated below.

Authority: 49 U.S.C. 30141 (a)(1) (A) and (b)(1); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: August 11, 1997.

Marilynne Jacobs,

Director, Office of Vehicle Safety Compliance.
[FR Doc. 97-21605 Filed 8-14-97; 8:45 am]

BILLING CODE 4910-59-P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. 97-053; Notice 1]

Notice of Receipt of Petition for Decision That Nonconforming 1992 and 1994-1997 BMW 750iL Passenger Cars Are Eligible for Importation

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice of receipt of petition for decision that nonconforming 1992 and 1994-1997 BMW 750iL passenger cars are eligible for importation.

SUMMARY: This document announces receipt by the National Highway Traffic Safety Administration (NHTSA) of a petition for a decision that 1992 and 1994-1997 BMW 750iL passenger cars that were not originally manufactured to comply with all applicable Federal motor vehicle safety standards are eligible for importation into the United States because (1) they are substantially similar to vehicles that were originally manufactured for importation into and sale in the United States and that were certified by their manufacturer as complying with the safety standards, and (2) they are capable of being readily altered to conform to the standards.

DATES: The closing date for comments on the petition is September 15, 1997.

ADDRESSES: Comments should refer to the docket number and notice number, and be submitted to: Docket Section, Room 5109, National Highway Traffic Safety Administration, 400 Seventh St., SW, Washington, DC 20590. (Docket hours are from 9:30 a.m. to 4 p.m.)

FOR FURTHER INFORMATION CONTACT: George Entwistle, Office of Vehicle Safety Compliance, NHTSA (202-366-5306).

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 30141(a)(1)(A), a motor vehicle that was not originally manufactured to conform to all applicable Federal motor vehicle safety standards shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States,

certified under 49 U.S.C. 30115, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this decision in the **Federal Register**.

Champagne Imports, Inc. of Lansdale, Pennsylvania ("Champagne") (Registered Importer 90-009) has petitioned NHTSA to decide whether 1992 and 1994-1997 BMW 750iL passenger cars are eligible for importation into the United States. The vehicles which Champagne believes are substantially similar are the 1992 and 1994-1997 BMW 750iL that were manufactured for importation into, and sale in, the United States and certified by their manufacturer, Bayerische Motoren-Werke, A.G., as conforming to all applicable Federal motor vehicle safety standards.

The petitioner claims that it carefully compared non-U.S. certified 1992 and 1994-1997 BMW 750iL passenger cars to their U.S. certified counterparts, and found the vehicles to be substantially similar with respect to compliance with most Federal motor vehicle safety standards.

Champagne submitted information with its petition intended to demonstrate that non-U.S. certified 1992 and 1994-1997 BMW 750iL passenger cars, as originally manufactured, conform to many Federal motor vehicle safety standards in the same manner as their U.S. certified counterparts, or are capable of being readily altered to conform to those standards.

Specifically, the petitioner claims that non-U.S. certified 1992 and 1994-1997 BMW 750iL passenger cars are identical to their U.S. certified counterparts with respect to compliance with Standard Nos. 102 *Transmission Shift Lever Sequence * * **, 103 *Defrosting and Defogging Systems*, 104 *Windshield Wiping and Washing Systems*, 105 *Hydraulic Brake Systems*, 106 *Brake Hoses*, 109 *New Pneumatic Tires*, 113 *Hood Latch Systems*, 116 *Brake Fluid*, 124 *Accelerator Control Systems*, 201

Occupant Protection in Interior Impact, 202 *Head Restraints*, 204 *Steering Control Rearward Displacement*, 205 *Glazing Materials*, 206 *Door Locks and Door Retention Components*, 207 *Seating Systems*, 209 *Seat Belt Assemblies*, 210 *Seat Belt Assembly Anchorages*, 212 *Windshield Retention*, 216 *Roof Crush Resistance*, 219 *Windshield Zone Intrusion*, and 302 *Flammability of Interior Materials*.

Additionally, the petitioner states that non-U.S. certified 1992 and 1994-1997 BMW 750iL passenger cars comply with the Bumper Standard found in 49 CFR part 581.

Petitioner also contends that non-U.S. certified 1992 and 1994-1997 BMW 750iL passenger cars are capable of being readily altered to meet the following standards, in the manner indicated:

Standard No. 101 *Controls and Displays*: (a) Substitution of a lens marked "Brake" for a lens with a noncomplying symbol on the brake failure indicator lamp; (b) installation of a seat belt warning lamp that displays the appropriate; (c) recalibration of the speedometer/odometer from kilometers to miles per hour.

Standard No. 108 *Lamps, Reflective Devices and Associated Equipment*: (a) Installation of U.S.—model headlamp assemblies; (b) installation of U.S.—model front and rear sidemarkers/reflector assemblies; (c) installation of U.S.—model taillamp assemblies; (d) installation of a center high mounted stop lamp.

Standard No. 110 *Tire Selection and Rims*: Installation of a tire information placard.

Standard No. 111 *Rearview Mirror*: Replacement of the passenger side rearview mirror.

Standard No. 114 *Theft Protection*: Installation of a warning buzzer microswitch and a warning buzzer in the steering lock assembly.

Standard No. 118 *Power Window Systems*: Rewiring of the power window system so that the window transport is inoperative when the ignition is switched off.

Standard No. 208 *Occupant Crash Protection*: (a) Installation of a U.S.—model seat belt in the driver's position, or a belt webbing actuated microswitch inside the driver's seat belt retractor; (b) installation of an ignition switch actuated seat belt warning lamp and buzzer; (c) replacement of the driver's and passenger's side air bags and knee bolsters if they are not U.S.—model components. The petitioner states that the vehicles are equipped with a combination lap and shoulder restraint that adjusts by means of an automatic

retractor and releases by means of a single push button in each front designated seating position, with a combination lap and shoulder restraint that releases by means of a single push button in each rear outboard designated seating position, and with a lap belt in the rear center designated seating position.

Standard No. 214 *Side Impact Protection*: Installation of reinforcing beams.

Standard No. 301 *Fuel System Integrity*: Installation of a rollover valve in the fuel tank vent line between the fuel tank and the evaporative emissions collection canister.

The petitioner also states that a vehicle identification number plate that meets the requirements of 49 CFR part 565 will be affixed to non-U.S. certified 1992, and 1994-1997 BMW 750iL passenger cars.

Interested persons are invited to submit comments on the petition described above. Comments should refer to the docket number and be submitted to: Docket Section, National Highway Traffic Safety Administration, Room 5109, 400 Seventh Street, SW., Washington, DC 20590. It is requested but not required that 10 copies be submitted.

All comments received before the close of business on the closing date indicated above will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition will be published in the **Federal Register** pursuant to the authority indicated below.

Authority: 49 U.S.C. 30141 (a)(1)(A) and (b)(1); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: August 11, 1997.

Marilynne Jacobs,

Director, Office of Vehicle Safety Compliance.
[FR Doc. 97-21606 Filed 8-14-97; 8:45 am]

BILLING CODE 4910-59-P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 33440]

Arkansas-Oklahoma Railroad Company—Trackage Rights Exemption—Union Pacific Railroad Company

Union Pacific Railroad Company (UP) will agree to lease trackage to Arkansas-Oklahoma Railroad Company (AOK)

over: (1) UP's Krebs Industrial Lead extending from the clearance point of the mainline switch at milepost 564.5 to the end of the Krebs Industrial Lead, and (2) UP's Shawnee Branch extending from milepost 364.96 to milepost 370.5.

The transaction is scheduled to be consummated on or after August 7, 1997.

The purpose of the trackage rights is to provide AOK railroad freight service on the Shawnee Branch at McAlester, OK, and the Krebs Industrial spur between McAlester, and Krebs, OK.

As a condition to this exemption, any employees affected by the trackage rights will be protected by the conditions imposed in *Norfolk and Western Ry. Co.—Trackage Rights—BN*, 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Ry., Inc.—Lease and Operate*, 360 I.C.C. 653 (1980).

This notice is filed under 49 CFR 1180.2(d)(7). If it contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 33440 must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, N.W., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Kelley E. O'Brien, Esq., Mayer, Brown & Platt, 2000 Pennsylvania Avenue, N.W., Washington, DC 20006–1881.

Decided: August 6, 1997.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 97–21720 Filed 8–14–97; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 33417]

Union Pacific Railroad Company— Trackage Rights Exemption—Southern Pacific Transportation Company

Southern Pacific Transportation Company (SP) has agreed to grant overhead trackage rights to Union Pacific Railroad Company over SP's east-west rail line known as the Fort Worth Branch extending from milepost 50.2, near Fort Worth, to milepost 0.0, near Garrett, and over SP's north-south rail line known as the Hearne Line

extending between milepost 261.2, near Dallas at Belt Junction, to milepost 97.0, near Bryan, a total distance of 214.82 miles in the State of Texas.

The transaction is scheduled to be consummated on or after the August 8, 1997 effective date of the exemption.

The purpose of the trackage rights is to facilitate efficient train operations in a one-way directional movement of trains.

As a condition to this exemption, any employees affected by the trackage rights will be protected by the conditions imposed in *Norfolk and Western Ry. Co.—Trackage Rights—BN*, 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Ry., Inc.—Lease and Operate*, 360 I.C.C. 653 (1980).

This notice is filed under 49 CFR 1180.2(d)(7). If it contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 33417 must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, N.W., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Joseph D. Anthofer, Esq., 1416 Dodge Street, #830, Omaha, NE 68179.

Decided: August 6, 1997.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 97–21719 Filed 8–14–97; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

August 4, 1997.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Pub. L. 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

Special Request: In order to conduct the opinion survey described below in

early September 1997, the Department of the Treasury is requesting that the Office of Management and Budget (OMB) review and approve this information collection by August 19, 1997. To obtain a copy of this study, please contact the Internal Revenue Service Clearance Officer at the address listed below.

Internal Revenue Service (IRS)

OMB Number: 1545–1432.

Project Number: M:SP:V 97–019–G.

Type of Review: Revision.

Title: IRS Marketing Materials Opinion Survey.

Description: The purpose of this survey is to collect information to determine the effectiveness of the materials advertising the TeleFile program.

Respondents: Individuals or households.

Estimated Number of Respondents: 340.

Estimated Burden Hours Per Response: 15 minutes.

Frequency of Response: Annually (1997, 1998, 1999).

Estimated Total Reporting Burden: 179 hours.

Clearance Officer: Garrick Shear (202) 622–3869, Internal Revenue Service, Room 5571, 1111 Constitution Avenue, NW., Washington, DC 20224.

OMB Reviewer: Alexander T. Hunt (202) 395–7860, Office of Management and Budget, Room 10226, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports, Management Officer.

[FR Doc. 97–21600 Filed 8–14–97; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

August 7, 1997.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Pub. L. 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

Bureau Of Alcohol, Tobacco And Firearms (BATF)

OMB Number: 1512-0119.
Form Number: ATF F 2149/2150 (5200.14).

Type of Review: Extension.

Title: Notice of Removal of Tobacco Products or Cigarette Papers, or Cigarette Tubes.

Description: Tobacco manufacturers or export warehouse proprietors are liable for tax on tobacco products removed from their premises. Tobacco products, cigarette papers and tubes may be removed without payment of tax for specific purposes. This form verifies these removals.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 221.

Estimated Burden Hours Per Respondent: 15 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 18,225 hours.

OMB Number: 1512-0162.

Form Number: ATF F 3067 (5210.9).

Type of Review: Extension.

Title: Inventory—Manufacturer of Tobacco Products.

Description: This form is necessary to determine the beginning and ending inventories of tobacco products at the premises of a tobacco products manufacturer. The inventory is recorded on this form by the proprietor and is used to determine tax liability, compliance with regulations and for protection of the revenue.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 34.

Estimated Burden Hours Per Respondent: 5 hours.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 170 hours.

OMB Number: 1512-0334.

Recordkeeping Requirement ID

Number: ATF REC 5150/3.

Type of Review: Extension.

Title: Usual and Customary Business Records Relating to Tax-Free Alcohol.

Description: Tax-free alcohol is used for nonbeverage purposes by educational organizations, hospitals, laboratories, etc. Records maintain spirits accountability and protect tax revenue and public safety.

Respondents: Not-for-profit institutions, Federal Government, State, Local or Tribal Government.

Estimated Number of Respondents: 4,560.

Estimated Burden Hours Per Respondent: 1 hour.

Frequency of Response: On occasion.
Estimated Total Reporting Burden: 1 hour.

OMB Number: 1512-0336.

Recordkeeping Requirement ID

Number: ATF REC 5150/2.

Type of Review: Extension.

Title: Letterhead Applications and Notices Relating to Denatured Spirits.

Description: Denatured spirits are used for nonbeverage industrial purposes in the manufacturer of personal/household products. Permits/Applications control the authorized uses and flow. Tax revenue and public safety is protected.

Respondents: Business or other for-profit, Not-for-profit institutions, State, Local or Tribal Government.

Estimated Number of Respondents: 3,111.

Estimated Burden Hours Per Respondent: 30 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 1,556 hours.

OMB Number: 1512-0358.

Recordkeeping Requirement ID

Number: ATF REC 5210/1.

Type of Review: Extension.

Title: Tobacco Products Manufacturers—Records of Operations.

Description: Tobacco manufacturers must maintain a system of records that provide accountability over tobacco products received and produced. Needed to ensure tobacco transactions can be traced, and ensure that tax liabilities have been totally satisfied.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 108.

Estimated Burden Hours Per Respondent: 150 hours.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 16,200 hours.

OMB Number: 1512-0368.

Recordkeeping Requirement ID

Number: ATF REC 5230/1.

Type of Review: Extension.

Title: Tobacco Products Importer or Manufacturer—Records of Large Cigar Wholesale Prices.

Description: Used by tobacco importers or manufacturers who import or make large cigars. Record is needed to verify wholesale prices of those cigars; tax is based on those prices. Ensures that all tax revenue due the government are collected.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 108.

Estimated Burden Hours Per Respondent: 2 hours, 30 minutes.

Frequency of Response: On occasion.
Estimated Total Reporting Burden: 252 hours.

Clearance Officer: Robert N. Hogarth (202) 927-8930, Bureau of Alcohol, Tobacco and Firearms, Room 3200, 650 Massachusetts Avenue, N.W., Washington, DC 20226.

OMB Reviewer: Alexander T. Hunt (202) 395-7860, Office of Management and Budget, Room 10202, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.
[FR Doc. 97-21601 Filed 8-14-97; 8:45 am]

BILLING CODE 4810-31-P

DEPARTMENT OF THE TREASURY**Submission to OMB for Review; Comment Request**

August 4, 1997.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Pub. L. 104-13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

Internal Revenue Service (IRS)

OMB Number: 1545-0991.

Form Number: IRS Form 8633.

Type of Review: Extension.

Title: Application to Participate in the Electronic Filing Program.

Description: Form 8633 will be used by tax preparers, electronic return collectors, software firms, service bureaus and electronic transmitters, as an application to participate in the electronic filing program covering individual income tax returns.

Respondents: Business or other for-profit, Not-for-profit institutions.

Estimated Number of Respondents: 50,000.

Estimated Burden Hours Per Respondent: 1 hour.

Frequency of Response: Annually.

Estimated Total Reporting Burden: 50,000 hours.

OMB Number: 1545-1543.

Revenue Procedure Number: Revenue Procedure 97-29.

Type of Review: Extension.

Title: Model Amendments and Prototype Program for SIMPLE IRAs.

Description: The revenue procedure (1) provides a model amendment that may be used prior to January 1, 1999, by a sponsor of a prototype IRA, (2) provides guidance to drafters of prototype SIMPLE IRAs on obtaining opinion letters, (3) provides permissive amendments to sponsors of non-SIMPLE IRAs, (4) announces the opening of a prototype program for SIMPLE IRA Plans, and (5) provides transitional relief.

Respondents: Business or other for-profit, Not-for-profit institutions.

Estimated Number of Respondents: 3,205.

Estimated Burden Hours Per

Respondent: 8 hours, 4 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 25,870 hours.

Clearance Officer: Garrick Shear, (202) 622-3869, Internal Revenue Service, Room 5571, 1111 Constitution Avenue, NW, Washington, DC 20224.

OMB Reviewer: Alexander T. Hunt, (202) 395-7860, Office of Management and Budget, Room 10226, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports, Management Officer.
[FR Doc. 97-21602 Filed 8-14-97; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Senior Executive Service; Departmental Performance Review Board

AGENCY: Treasury Department.

ACTION: Notice of members of the Departmental Performance Review Board (PRB).

SUMMARY: Pursuant to 5 U.S.C. 4314(c)(4), this notice announces the appointment of members of the Departmental PRB. The purpose of this PRB is to review and make recommendations concerning proposed performance appraisals, ratings, bonuses and other appropriate personnel actions for incumbents of SES positions for which the Secretary or Deputy Secretary is the appointing authority. These positions include SES bureau heads, deputy bureau heads and certain other positions. The Board will perform PRB functions for other key bureau positions if requested.

Composition of Departmental PRB

The Board shall consist of at least three members. In the case of an appraisal of a career appointee, more than half the members shall consist of

career appointees. The names and titles of the PRB members are as follows:

George Muñoz, Assistant Secretary (Management) and Chief Financial Officer—Chairperson
Gerald Murphy, Fiscal Assistant Secretary
John P. Simpson, Deputy Assistant Secretary (Regulatory, Tariff and Trade Enforcement)
Alex Rodriguez, Deputy Assistant Secretary (Administration)
William H. Gillers, Director, Office of Management Advisory Services
James E. Johnson, Assistant Secretary (Enforcement)
David A. Lebryk, Acting Deputy Assistant Secretary (Human Resources)
Margrethe Lundsager, Deputy Assistant Secretary (Trade and Investment Policy)
Mary E. Chaves, Director, Office of International Debt Policy
Jane L. Sullivan, Director, Office of Information Resources Management
Joan Affleck-Smith, Director, Office of Financial Institutions Policy
John W. Magaw, Director, Bureau of Alcohol, Tobacco and Firearms
Samuel H. Banks, Deputy Commissioner, U.S. Customs Service
Vincette L. Goerl, Assistant Commissioner (Finance)/CFO, U.S. Customs Service
Douglas M. Browning, Assistant Commissioner (International Affairs), U.S. Customs Service
Lewis C. Merletti, Director, U.S. Secret Service
W. Ralph Basham, Assistant Director, Administration, U.S. Secret Service
John P. Mitchell, Deputy Director, U.S. Mint
Richard B. Calahan, Deputy Inspector General
Russell D. Morris, Commissioner, Financial Management Service
Larry E. Rolufs, Director, Bureau of Engraving and Printing
Michael P. Dolan, Acting Commissioner, Internal Revenue Service
David A. Mader, Chief Officer, Management and Administration, Internal Revenue Service
Richard L. Gregg, Commissioner, Bureau of the Public Debt
Kenneth R. Schmalzbach, Assistant General Counsel (General Law and Ethics)
Roberta K. McInerney, Assistant General Counsel (Banking and Finance)

DATES: Membership is effective on August 15, 1997.

FOR FURTHER INFORMATION CONTACT: Ronald A. Glaser, Department of the Treasury, Acting Director, Office of Personnel Policy, Annex Building,

Room 4150, Pennsylvania Avenue at Madison Place, NW., Washington, DC 20220, Telephone: (202) 622-1890.

This notice does not meet the Department's criteria for significant regulations.

Ronald A. Glaser,

Acting Director, Office of Personnel Policy.

[FR Doc. 97-21635 Filed 8-14-97; 8:45 am]

BILLING CODE 4810-25-M

DEPARTMENT OF THE TREASURY

Bureau of the Public Debt

Proposed Collection: Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Pub. L. 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently the Bureau of the Public Debt within the Department of the Treasury is soliciting comments concerning the Request for Reissue of U.S. Savings Bonds/Notes in name of trustee of personal trust estate.

DATES: Written comments should be received on or before October 14, 1997, to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of the Public Debt, Vicki S. Thorpe, 200 Third Street, Parkersburg, WV 26106-1328.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Vicki S. Thorpe, Bureau of the Public Debt, 200 Third Street, Parkersburg, WV 26106-1328, (304) 480-6553.

SUPPLEMENTARY INFORMATION:

Title: Request For Reissue Of United States Savings Bonds/Notes In Name Of Trustee Of Personal Trust Estate.

OMB Number: 1535-0009.

Form Number: PD F 1851.

Abstract: The information is requested to support a request for reissue of savings bonds/notes in the name of the trustee of a personal trust estate.

Current Actions: None.

Type of Review: Extension.

Affected Public: Individuals.

Estimated Number of Respondents: 55,000.

Estimated Time Per Respondent: 15 minutes.

Estimated Total Annual Burden Hours: 13,750.

REQUEST FOR COMMENTS: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: August 11, 1997.

Vicki S. Thorpe,

Manager, Graphics, Printing and Records Branch.

[FR Doc. 97-21703 Filed 8-14-97; 8:45 am]

BILLING CODE 4810-39-P

DEPARTMENT OF THE TREASURY

Bureau of the Public Debt

Proposed Collection: Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Pub. L. 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently the Bureau of the Public Debt within the Department of the Treasury is soliciting comments concerning the Payments by banks and other financial institutions of United States Savings Bonds/Notes.

DATES: Written comments should be received on or before October 14, 1997, to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of the Public Debt, Vicki S. Thorpe, 200 Third Street, Parkersburg, WV 26106-1328.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the form and instructions should be directed to Vicki S. Thorpe, Bureau of the Public Debt, 200 Third Street, Parkersburg, WV 26106-1328, (304) 480-6553.

SUPPLEMENTARY INFORMATION:

Title: Payments by Banks and Other Financial Institutions of United States Savings Bonds and Notes (Freedom Shares).

OMB Number: 1535-0087.

Abstract: Qualified financial institutions are authorized to redeem eligible savings bonds and notes, and receive settlement through the Federal Reserve check collection system.

Current Actions: None.

Type of Review: Extension.

Affected Public: Businesses or other for-profit.

Estimated Number of Respondents: 48,430.

Estimated Time Per Respondent: 4 seconds.

Estimated Total Annual Burden Hours: 78,349.

REQUEST FOR COMMENTS: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: August 11, 1997.

Vicki S. Thorpe,

Manager, Graphics, Printing and Records Branch.

[FR Doc. 97-21704 Filed 8-14-97; 8:45 am]

BILLING CODE 4810-39-P

DEPARTMENT OF THE TREASURY

Bureau of the Public Debt

Proposed Collection: Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Pub. L. 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently the Bureau of the Public Debt within the Department of the Treasury is soliciting comments concerning the Regulations Governing Book-Entry Treasury Bonds, Notes and Bills.

DATES: Written comments should be received on or before October 14, 1997, to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of the Public Debt, Vicki S. Thorpe, 200 Third Street, Parkersburg, WV 26106-1328.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the form and instructions should be directed to Vicki S. Thorpe, Bureau of the Public Debt, 200 Third Street, Parkersburg, WV 26106-1328, (304) 480-6553.

SUPPLEMENTARY INFORMATION:

Title: Regulations Governing Book-Entry Treasury Bonds, Notes and Bills.

OMB Number: 1535-0068.

Abstract: The information is requested to establish an investor's Treasury account; to dispose of securities upon the owner's request; and, to determine entitlement to securities.

Current Actions: None.

Type of Review: Extension.

Affected Public: Individuals, Businesses or other for-profit, and state or local governments.

Estimated Number of Respondents: 75,000.

Estimated Time Per Respondent: 7 minutes.

Estimated Total Annual Burden Hours: 8,775.

REQUEST FOR COMMENTS: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper

performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: August 11, 1997.

Vicki S. Thorpe,

Manager, Graphics, Printing and Records Branch.

[FR Doc. 97-21705 Filed 8-14-97; 8:45 am]

BILLING CODE 4810-39-P

DEPARTMENT OF THE TREASURY

Bureau of the Public Debt

Proposed Collection: Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Pub. L. 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently the Bureau of the Public Debt within the Department of the Treasury is soliciting comments concerning the extension of information collections under the regulations which were issued pursuant to the Government Securities Act.

DATES: Written comments should be received on or before October 14, 1997, to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of the Public Debt, Vicki S. Thorpe, 200 Third Street, Parkersburg, WV 26106-1328.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Vicki S. Thorpe, Bureau of the Public Debt, 200 Third Street, Parkersburg, WV 26106-1328, (304) 480-6553.

SUPPLEMENTARY INFORMATION:

Title: Government Securities Act Regulations.

OMB Number: 1535-0089.

Abstract: The information collections are contained within the regulations issued pursuant to the Government Securities Act (GSA), as amended (15 U.S.C. 780-5), which require government securities brokers and dealers to make and keep certain records concerning their business activities and their holdings of securities, to submit financial reports, and to make certain disclosures to investors. The regulations also require depository institutions to keep certain records of non-fiduciary custodial holdings of government securities. The regulations and associated collections are fundamental to customer protection and dealer financial responsibility.

Current Actions: None.

Type of Review: Extension.

Affected Public: Government securities brokers and dealers and depository institutions.

Estimated Number of Respondents: 35,506.

Estimated Total Annual Burden Hours: 393,667.

REQUEST FOR COMMENTS: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: August 11, 1997.

Vicki S. Thorpe,

Manager, Graphics, Printing and Records Branch.

[FR Doc. 97-21706 Filed 8-14-97; 8:45 am]

BILLING CODE 4810-39-P

DEPARTMENT OF VETERANS AFFAIRS

Enhanced-Use Development at the VAMC, Durham, NC

AGENCY: Department of Veterans Affairs.

ACTION: Notice of designation.

SUMMARY: The Secretary of the Department of Veterans Affairs is designating the Veterans Affairs Medical Center at Durham, North Carolina for an Enhanced-Use development. The Department intends to enter into a long-term lease of real property under VA's control and jurisdiction with a public or private developer/operator to finance and maintain a mixed-use development. As consideration for the long-term use of VA's capital assets, the Medical Center would receive space or facilities for primary care, research, and additional parking at no capital cost to VA.

FOR FURTHER INFORMATION CONTACT:

Mr. Anatolij Kushnir, Director, Office of Asset and Enterprise Development (189), Department of Veterans Affairs, Veterans Health Administration, Office of Facilities Management, 810 Vermont Avenue, NW, Washington, DC, 20420, (202) 565-4307.

SUPPLEMENTARY INFORMATION: 38 U.S.C. Sec. 8161 *et seq.*, specifically provides that the Secretary may enter into an Enhanced-Use Lease if the Secretary determines that at least part of the use of the property will be to provide appropriate space for an activity contributing to the mission of the Department; the lease will not be inconsistent with and will not adversely affect the mission of the Department; and the lease will enhance the property. This project meets these requirements.

Approved: August 7, 1997.

Hershel W. Gober,

Secretary-Designate.

[FR Doc. 97-21604 Filed 8-14-97; 8:45 am]

BILLING CODE 8320-01-M

DEPARTMENT OF VETERANS AFFAIRS

The Enhanced-Use Development of VAMC Portland, OR

AGENCY: Department of Veterans Affairs.

ACTION: Notice of designation.

SUMMARY: The Secretary of the Department of Veterans Affairs is designating the Portland, OR, Department of Veterans Affairs Medical Center (VAMC) for an Enhanced-Use development. The Department intends to enter into a long-term lease of real property with the Vancouver (WA) Housing Authority. The Vancouver Housing Authority, in turn, will establish a newly formed 501(C)(3) corporation which will become the managing general partner of the project, and will finance, design, construct, and manage a Single Room Occupancy

facility to consist of 126 units of single room occupancy and studio apartments. Fifty percent (63 beds) of the facility will be designated as veteran preference, to provide affordable housing for homeless veterans with occupants to be referred and case managed by the Portland VA Medical Center.

FOR FURTHER INFORMATION CONTACT: Jacob Gallun, Asset and Enterprise Development Office (189), Veterans

Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC, 20420, (202) 565-4307.

SUPPLEMENTARY INFORMATION: 38 U.S.C. Sec 8161 *et seq.*, specifically provides that the Secretary may enter into an Enhanced-Use lease, if the Secretary determines that at least part of the use of the property under the lease will be to provide appropriate space for an

activity contributing to the mission of the Department, the lease will not be inconsistent with and will not adversely affect the mission of the Department; and the lease will enhance the property. This project meets these requirements.

Approved: August 5, 1997.

Hershel W. Gober,

Secretary-Designate.

[FR Doc. 97-21603 Filed 8-14-97; 8:45 am]

BILLING CODE 8320-01-M

Final Rule

Friday
August 15, 1997

Part II

Environmental Protection Agency

40 CFR Parts 51 and 93
Transportation Conformity Rule
Amendments: Flexibility and Streamlining;
Final Rule

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Parts 51 and 93**

[FRL-5871-4]

RIN 2060-AG16

Transportation Conformity Rule Amendments: Flexibility and Streamlining**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: Today EPA promulgates a clarified and more 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 the national ambient air quality standards.

The conformity rule changes promulgated today result from the experience that EPA, the Department of Transportation (DOT), and state and local air and transportation officials have had with implementation of the rule since it was first published in November of 1993. While these changes clarify the rule and in some cases offer increased flexibility, they will not result in any negative change in health and environmental benefits.

Today's rule gives state and local governments more authority in selecting the performance measures used as tests of conformity and more discretion when a transportation plan does not conform to a SIP. For example, the rule allows motor vehicle emissions budgets in a submitted SIP to be used to determine conformity instead of the "build/no-build" test, and rural areas can choose among several conformity tests to address the time period after that covered by the SIP.

EFFECTIVE DATE: September 15, 1997.

ADDRESSES: Materials relevant to this rulemaking are contained in Docket No. A-96-05. The docket is located in room M-1500 Waterside Mall (ground floor) at the Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. The docket may be inspected from 8 a.m. to 5:30 p.m., Monday through Friday, including all non-government holidays. For information on electronic availability see Supplementary Information.

FOR FURTHER INFORMATION CONTACT: Meg Patulski, Transportation and Market Incentives Group, Regional and State Programs Division, U.S. Environmental Protection Agency, 2565 Plymouth Road, Ann Arbor, MI 48105, patulski.meg@epamail.epa.gov. (313) 741-7842.

SUPPLEMENTARY INFORMATION:**Regulated Entities**

Entities potentially regulated by the conformity rule are those which adopt, approve, or fund transportation plans, programs, or projects under title 23 U.S.C. or title 49 U.S.C. 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 ..	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 rule. 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 requirements in § 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.

Electronic Availability

The final rule is also available electronically from the EPA internet web site. Users are able to access and download files on their first call using a personal computer according to the following information:

Internet Web Sites

<http://www.epa.gov/docs/fedrgstr/EPA-AIR/>

(either select desired date or use Search feature)

Or

<http://www.epa.gov/OMSWWW/>
(look in What's New or under the Conformity file area)

The electronic version of this final rule should be available today on any of the above-listed sites. Please note that due to differences between the software used to develop the document and the software into which the document may be downloaded, changes in format, page length, etc. may occur.

The contents of this preamble are listed in the following outline:

- I. Background on Transportation Conformity
- II. Replacement of Build/No-build Test With Submitted SIPs
- III. Other Comments on Conformity Tests
- IV. Conformity Tests for Areas That Are Not Required to Submit SIPs
- V. Rural Nonattainment and Maintenance Areas
- VI. Mismatch in SIP/Transportation Plan Timeframe
- VII. Non-federal Projects
- VIII. Deadline for Use of Network Models and Affected Areas
- IX. Content of Network Modeling Requirements in Serious and Above Ozone and CO Areas
- X. Adding Non-Exempt Projects to the Plan/TIP Without Regional Analysis
- XI. Consequences of SIP Disapproval
- XII. Traffic Signal Synchronization
- XIII. Conformity SIPs
- XIV. Hot-spot Tests
- XV. TCM Flexibility
- XVI. Conformity and the Proposed NAAQS Revisions
- XVII. Minor Changes to the Rule
- XVIII. Administrative Requirements

I. Background on Transportation Conformity

Today's action amends 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 air quality 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. This experience has led to the streamlining, clarification, and new opportunities for flexibility found in today's rule, which is the third of a series of 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 conformity determinations for 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 (defined below in section XI.).

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 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 to be consistent with the NO_x requirements of the Clean Air Act and previous commitments made by EPA.

The second set of amendments also allowed any transportation control measure (TCM) from an approved SIP to proceed during a conformity lapse, although EPA stated that it did not intend to approve SIPs containing TCMs that have not been coordinated through the transportation planning process, as required by 23 CFR part 450 and 49 CFR part 613. The Clean Air Act and the Intermodal Surface Transportation Efficiency Act require that an integrated transportation/air quality planning

process be used to identify effective TCMs and ensure their funding sources.

The Notice of Proposed Rulemaking for today's rule was published in the **Federal Register** on July 9, 1996 (61 FR 36111). This proposal was undertaken in response to several issues raised by conformity implementers and other interested parties. EPA worked closely with conformity stakeholders in developing the proposal, and had input from the National Governors' Association (NGA), the Environmental Council of States (ECOS), state DOTs, state environmental agencies, MPOs, environmentalists, industry groups, other public interest groups, and DOT. In 1995, meetings to discuss potential amendments to the conformity rule were held by NGA and ECOS as well as the EPA. EPA developed draft regulatory language in response and sought comment from stakeholders.

The proposal's comment period ended September 9, 1996. EPA held a public hearing for this proposal on August 6, 1996. EPA received more than 50 comments from a variety of interests, including MPOs, state and local air quality agencies, state DOTs, NGA, and environmentalists. Copies of comments in their entirety can be obtained from the docket for this rule (see **ADDRESSES**). The docket also includes a complete Response to Comments document for this rule.

Since 1993, the transportation conformity rule has been included in 40 CFR part 51 and largely duplicated in 40 CFR part 93. In order to streamline the CFR and eliminate this duplication, the only section of today's conformity rule that remains in 40 CFR part 51 is § 51.390, which requires a conformity SIP revision. Part 51 is entitled, "Requirements for Preparation, Adoption, and Submittal of Implementation Plans." The remainder of the conformity rule is included in 40 CFR part 93, which is entitled, "Determining Conformity of Federal Actions to State or Federal Implementation Plans."

II. Replacement of Build/No-Build Test With Submitted SIPs

A. Description of Final Rule

Today's action finalizes the proposal to eliminate the build/no-build test and other 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 SIP submission and the adequacy of its motor vehicle emissions budget(s) for conformity purposes. This final rule also includes regulatory text from the proposal's preamble which establishes

the minimum criteria that must be satisfied in order for EPA to find a submitted motor vehicle emissions budget adequate for transportation conformity purposes. EPA clarifies today that submitted SIPs must already meet these minimum criteria in order to be approved; EPA is not imposing any new requirements for submitted SIPs.

EPA described the minimum adequacy criteria in the preamble to the proposal (61 FR 36114, July 9, 1996), and they are outlined as follows. In accordance with this final rule, an area's submitted SIP must be endorsed by the Governor (or his/her designee) and subject to a public hearing in order for EPA to find the submitted SIP adequate. Prior to submitting the SIP, consultation between federal, state, and local agencies must occur. SIP development must be documented and any technical support information needed to review the adequacy of the SIP must be submitted to EPA. In addition, any concerns stated by EPA must be addressed before the SIP is submitted. The emissions budget(s) must be clearly identified and precisely quantified. When considered with point, area, and mobile sources, the emissions budget(s) must be consistent with applicable requirements for reasonable further progress (RFP), attainment, or maintenance, depending upon the particular SIP submission. The SIP budget(s) must be consistent with the area's emissions inventory for all sources and a clear relationship among the budget(s), control measures and emissions inventory must be shown.

In addition, submitted SIPs must explain and document any changes to previously submitted motor vehicle emissions budgets and control measures; impacts on point and area source emissions; any changes to established safety margins; and reasons for the changes, including the basis for any changes related to emission factors or estimates of vehicle miles traveled (VMT). EPA is defining safety margin in this final rule to be the amount by which the total projected emissions from all sources of a given pollutant are less than the total emissions that would satisfy the applicable Clean Air Act requirement for RFP, attainment, or maintenance.

EPA will interpret these adequacy criteria to mean that if a submitted SIP's emissions budgets rely upon additional control measures to demonstrate RFP, attainment, or maintenance, such new control measures must be specified in the SIP submission. The submitted SIP would need to quantify the emissions impacts of any new control measures in its revised SIP, and at a minimum,

include commitments by appropriate agencies for adoption and implementation schedules, in addition to draft regulations or other relevant documents. These are minimum criteria for adequacy of emissions budgets for conformity purposes; an approvable SIP must have adopted and enforceable control measures.

Prior to EPA determining the adequacy of a submitted SIP budget, EPA will also review documentation from the state's public comment hearing on the SIP submission and the state's responses to the public comments received. This documentation is currently required to be included in the SIP package when it is submitted to EPA for its review. EPA will send a letter to the state documenting EPA's finding of adequacy or inadequacy, including EPA's consideration of public comment.

The conformity adequacy review is separate from EPA's completeness review of a submitted SIP for purposes of SIP processing. In addition, EPA's 45-day adequacy review should not be used to prejudge EPA's ultimate approval or disapproval of the SIP. As stated in the proposal, EPA cannot ensure that a submitted SIP is consistent with RFP, attainment, or maintenance until EPA has completed its formal review process and the SIP has been approved or disapproved through notice-and-comment rulemaking. Although the minimum criteria for adequacy allow EPA to make a cursory review of the submitted motor vehicle emissions budget for conformity purposes, EPA recognizes that other elements must also be in the SIP for it to ultimately be approved. Therefore, a budget that is found adequate in the 45-day review period could later be disapproved when reviewed with the entire SIP submission.

EPA will find a submitted motor vehicle emissions budget inadequate if the submitted budget does not meet the minimum criteria. However, the criteria included in the conformity rule are not intended to be a comprehensive definition of an adequate SIP for SIP approval purposes.

EPA also clarifies that the 45-day adequacy review period begins upon the receipt of the SIP submission in the EPA regional office.

Areas that submit SIPs after the effective date of this final rule will be able to use their SIP budget(s) within 45 days of submission or sooner if EPA finds them adequate. Areas that submit SIPs prior to the effective date of this final rule can use those SIPs according to the requirements of § 51.448(a)(2)/§ 93.128(a)(2) as amended on November 14, 1995 (60 FR 57179). According to

these sections, areas can use submitted SIP budgets beginning 90 days after submission unless EPA finds them inadequate; areas can use them earlier if EPA declares them adequate.

EPA's 90-day review period that is described in § 51.448(a)(2)/§ 93.128(a)(2) of the previous conformity rule may have used different standards for adequacy than are being outlined in this final rule, because under the previous rule the build/no-build test applied in addition to the submitted budget. SIPs that EPA believed adequate under that rule may not be adequate if they are the sole test of conformity. As a result, EPA may use the adequacy criteria of this final rule to re-examine SIPs that were submitted before this final rule and have not yet been approved. EPA intends to complete this re-examination within 45 days after the effective date of this final rule. During this time, areas will continue using their SIPs that have been submitted for more than 90 days; EPA's possible re-examination will not delay or in any way interfere with areas determining conformity unless EPA finds the SIP inadequate.

B. Rationale and Response to Comments

Most commenters agreed that the emission reduction tests should not be required once a SIP is submitted. The majority of commenters agreed that compared to the budget test, the value of the build/no-build test is limited. Commenters believed that the proposed flexibility would streamline conformity and use state and local resources more efficiently. Most commenters also supported the proposal's reduction of the adequacy review period for a submitted SIP from 90 to 45 days.

However, some commenters were concerned that submitted budgets may not be able to fully satisfy the purpose of the emission reduction tests, which is to ensure that annual emissions will be reduced and/or that violations will not be created or worsened (see Clean Air Act sections 176(c)(3)(A)(iii) and (c)(1)(B)). Specifically, some commenters stated that the proposed EPA review period would not be sufficient to ensure the adequacy of submitted budgets because the proposal did not establish any objective criteria for adequacy in the regulatory language, or provide an opportunity for public comment on EPA's adequacy finding. Some argued that the absence of adequacy criteria for submitted budgets could lead to the submission of inflated budgets (not based on credible, quantifiable attainment demonstrations) for the convenience of determining conformity. Commenters felt that although these SIPs would ultimately

not prove acceptable, they could allow projects to proceed during EPA's rulemaking to disapprove the SIP. This could also lead to delays in attainment. Another commenter was concerned that the lack of objective criteria for adequacy in the rule would make EPA more vulnerable to political pressure to approve inadequate budgets.

EPA agrees that if submitted budgets are to replace the build/no-build test as the primary measure of conformity, the criteria by which EPA will judge their adequacy must be clearly articulated in the rule. EPA has done so in this final action, and these criteria are those described in the preamble to the proposal. In addition, submitted SIPs must already meet these criteria in order for EPA to ultimately approve them. Since the criteria included in this final rule are the same as those described in the proposal and thus subjected to public comment, EPA does not believe a reproposal is necessary prior to adding the criteria to the regulatory language.

EPA also agrees that the public should be given the opportunity to comment on the adequacy of a submitted SIP. Some commenters suggested requiring public notice of submitted budgets and a 60-day period during which the public could file objections and present arguments to EPA for its consideration in its adequacy review. However, because the state already holds a public hearing on the draft SIP before submitting it to EPA, EPA believes the public has sufficient opportunity to comment at the state level on the adequacy of the budgets contained in the SIP. EPA believes the rule now addresses commenters' concerns by requiring EPA to review and consider the compilation of public comment that the state is already required to include with any SIP submission. EPA will document its consideration of such comments in the letter to the state indicating the adequacy of the submitted budget(s).

Commenters also expressed concern that EPA is not even obligated to determine adequacy, since a submitted budget can be used even if EPA has not determined adequacy within the 45-day review period. However, EPA is committed to helping ensure that conformity and future transportation investment decisions are made using the best possible SIPs, and EPA intends to review all submitted SIPs within the 45-day period.

Some commenters stated that EPA may not establish a motor vehicle emissions budget as a legally enforceable obligation without following the notice and comment procedures of the Administrative

Procedure Act (APA). EPA believes that it is appropriate not to provide notice and comment for adequacy determinations for submitted SIPs, since these determinations are only administrative reviews and not substantive rules. When EPA reviews a SIP for completeness, EPA does not perform a notice-and-comment rulemaking. EPA believes that determining adequacy is more similar to completeness review than a SIP approval action, in that adequacy determinations are merely administrative applications of established criteria to emissions budgets. For these reasons, EPA is not requiring notice and comment for its 45-day adequacy review period. However, EPA believes the commenters' concerns relating to public review under the APA are addressed because EPA has established the criteria for determining adequacy through this final rule, which has gone through APA notice and comment procedures. In addition, EPA is ensuring that public comment on adequacy of individual budgets is considered through review of comments submitted to the state.

In addition to specific criteria for adequacy, some commenters wanted to limit the grandfathering of new projects found to conform on the basis of a submitted SIP's budget. A "grandfathered" project can proceed without further conformity determinations (see § 93.102(c) for more details). Transportation projects are currently grandfathered after a National Environmental Policy Act (NEPA) document is approved and a project-level conformity determination is made. In order for a project-level conformity determination to occur, a conforming plan and TIP must be in place at the time of the determination.

Under the commenters' scenario, projects would only be grandfathered when a project agreement authorizing federal funds pursuant to 23 USC 110 or 49 USC 5309 has been executed. This would grandfather projects later in the transportation planning process than is currently the case. Changing the grandfathering in this manner would make it more likely that local and state planners could halt a project(s) if the SIP is ultimately disapproved. The commenters were concerned that a submitted SIP's budget may not contain the necessary emission reductions for demonstrating conformity in the future. If EPA declared a budget adequate during the 45-day review period but later disapproved it, commenters were concerned that an area may have difficulty demonstrating conformity in the future if all the projects planned

according to that budget are grandfathered.

EPA believes that current grandfathering requirements are appropriate and should not be changed. EPA has always believed that there should only be one point in the transportation planning process at which a project-level conformity determination is necessary. This maintains stability and efficiency in the transportation planning process.

Completion of the NEPA process is the step EPA has selected historically for grandfathering transportation projects for several reasons. Making a determination under NEPA is clearly an action to support or approve an activity, and the Clean Air Act does not allow a federal agency to take such an action without a conformity determination. In addition, an air quality analysis is already required by NEPA. To require this analysis again at a later date may create redundancies in the transportation process and cause state and local resources to be used less efficiently.

EPA is partially addressing these stakeholder concerns by maintaining adverse conformity consequences in the case of SIP disapproval without a protective finding. As described in section XI. of this preamble, today's final rule does not allow any new projects to be added to the plan or TIP beginning 120 days after a SIP is disapproved without a protective finding. In cases of a SIP disapproval without a protective finding, areas would only be able to advance projects in the first three years of the currently conforming plan and TIP. Therefore, although EPA is not changing the grandfathering of projects after a SIP is submitted, there are real consequences if a submitted SIP is ultimately found to have emissions budgets that will not result in reasonable further progress or attainment. In addition, EPA believes that with the adequacy requirements added to the rule and the review of submitted public comments, it is less likely that budgets which EPA finds adequate will ultimately be disapproved.

III. Other Comments on Conformity Tests

A. Implementation of Budget Test: Submitted vs. Approved Budgets

Some commenters stated that EPA should allow submitted SIP budgets to override those in approved SIPs for years directly addressed by the approved SIP. These commenters believed that newly submitted SIPs often provide a more realistic picture of

the future than approved SIPs. Some believed that, unlike approved SIPs, newly submitted SIPs are more accurate because they are based on an area's latest planning assumptions.

Although EPA acknowledges that using updated budgets may be preferable, EPA does not believe that it is legal to allow a submitted SIP to supersede an approved SIP for years addressed by the approved SIP. As stated in the proposal, Clean Air Act section 176(c) specifically requires conformity to be demonstrated to approved SIPs. SIP revisions that EPA has approved under Clean Air Act section 110 are enforceable and cannot be relieved by a submission, even if that submission utilizes better data. Approved SIP budgets have also 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. Some commenters suggested that EPA should institute another adequacy review process (similar to that being finalized today for submitted SIPs) which could ensure that submitted SIPs are consistent with attainment or maintenance. However, this type of process does not resolve the legal prohibition on overriding approved SIPs, and it would not be possible to determine whether submitted SIPs are consistent with attainment or maintenance without EPA's full public review and approval process. Although submitted SIPs cannot override approved SIPs for years addressed by the approved SIP, EPA did clarify in the proposal and this final rule that submitted SIPs can be used for years later than those addressed by an approved SIP.

Others suggested that, if EPA could not allow submitted SIPs to override approved SIPs, then EPA should require conformity determinations to be done using the same models and inputs that were used in the approved SIP. However, Clean Air Act section 176(c)(1)(B)(iii) requires that conformity determinations "be based on the most recent estimates of emissions, and such estimates shall be determined from the most recent population, employment, travel, and congestion estimates." As stated in the preamble to the 1993 conformity rule (58 FR 62210), it is expected that over time conformity determinations will deviate from the SIP's assumptions regarding VMT growth, demographics, trip generation, etc. Conformity is intended to ensure that a SIP's emission targets are achieved given the most recent planning assumptions. If conformity cannot be demonstrated using the most recent

planning assumptions, either the SIP or the transportation plan and TIP must be adjusted.

Even though an approved SIP can be changed if another SIP is submitted and approved by EPA, some commenters believed that EPA's review and approval of submitted SIPs would not occur in a timely manner. The commenters urged EPA to conduct expedited review and approval of submitted SIPs (e.g., 6- to 12-month timeframe), especially those that are revisions of the currently approved SIP.

EPA recognizes these stakeholder concerns and has already made expedited approval processes, such as parallel processing, available to states. In parallel processing, states can develop a draft SIP revision with close EPA involvement. If all approvability issues are resolved prior to submitting the SIP to EPA, the state and EPA then request public comment on the SIP at the same time. If no adverse comment is received, EPA then finalizes approval as soon as possible after formal state adoption and submittal, as long as no substantive changes have occurred and the package is still approvable. Parallel processing is encouraged when SIP revisions are straightforward, especially when assumptions are updated and new, significant control measures are unnecessary. In addition to parallel processing, EPA can use direct final rulemaking to approve SIPs more quickly in cases where EPA does not expect adverse comment.

B. VMT Comparison as Substitute for Budget Test

A few commenters recommended that areas be given the option to use a VMT comparison test instead of the budget test, especially if data sets and modeling used in the SIP are different than those used in the plan and TIP. These commenters argued that the present budget test's analytical inconsistencies could be eliminated if areas were allowed to replace the budget test with a comparison of the projected vehicle travel activity in the plan/TIP and that assumed in the SIP. If the projected VMT in the plan/TIP is consistent with that in the SIP, the commenters argued that Clean Air Act conformity requirements would be met.

In order to meet the "VMT test," commenters said that areas would have to demonstrate that: a) vehicle trips, VMT, and number of vehicles projected in the proposed plan/TIP have not exceeded these projections in the SIP; and, b) the transportation system in the proposed plan and TIP, and vehicle speed distributions on that system, are found through the consultation process

to be in reasonable agreement with the system and speed distributions assumed in the SIP. Commenters argued that this idea is supported by Clean Air Act section 176(c)(2)(A) which says that "emissions expected from the implementation of plans and programs are consistent with estimates of emissions from motor vehicles and necessary emissions reductions contained in the applicable implementation plan * * *". If an MPO's "most recent population, employment, travel and congestion estimates" (section 176(c)(1)) do not exceed estimates of these parameters in the SIP, the commenters believe that the transportation community has fulfilled its Clean Air Act requirements.

EPA believes that this is not the correct legal interpretation of Clean Air Act section 176(c)(2)(A), and consequently, a VMT-based test is not a viable substitute for the budget test. As cited by the commenters, section 176(c)(2)(A) emphasizes that the projected emissions from the plan and TIP must be consistent with emissions targets in the SIP. Emissions estimates depend on numerous factors other than VMT, such as travel speed, fuels, inspection and maintenance (I/M), or other technological factors, and thus emissions could decrease even where VMT increases or vice-versa. Therefore, a VMT-based test could possibly make it more difficult for some areas to demonstrate conformity. For example, an area with high VMT growth could have difficulty passing a VMT-based test, even though it might have a cleaner fleet of vehicles resulting from electric vehicles or a successful I/M program. For all of these reasons, EPA is not offering a VMT-based test in this final rule.

IV. Conformity Tests for Areas That Are Not Required to Submit SIPs

A. Description of Final Rule

Today's action finalizes many of the options that were proposed for demonstrating conformity in areas that are not required to submit control strategy SIPs. The July 9, 1996 proposal outlined three options for determining conformity in these types of areas: (1) create a budget through the SIP process and use the budget test; (2) create a default budget based on clean data in areas that have achieved the standard but have not submitted a maintenance plan; or (3) use either the build/no-build or "no-greater-than-1990" emission reduction test. Today's final rule keeps the first and third proposed options, while limiting the second option.

Areas that are not required to submit control strategy SIPs include: 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. In addition, some moderate and above ozone nonattainment areas that are meeting the 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 Demonstrations, and Related Requirements for Ozone Nonattainment Areas Meeting the Ozone National Ambient Air Quality Standard" for more information about this small number of ozone areas.)

Under the November 1993 transportation conformity rule, all areas that are not required to submit control strategy SIPs had two options for demonstrating conformity. They could choose between satisfying both emission reduction tests (i.e., the build/no-build and less-than-1990 tests) or submitting a SIP and using the budget test. Areas that decided to choose the latter option, under the former conformity rule, were required to perform the build/no-build and less-than-1990 tests until the submitted SIP was approved.

According to this final rule, all areas that are not required to submit control strategy SIPs can demonstrate conformity by using either the build/no-build test or no-greater-than-1990 test (i.e., emissions must be equal to or less than 1990 emissions); or, by submitting a SIP through the regular SIP process and using the budget test 45 days after submittal, provided EPA has not found the submitted SIP inadequate. The SIP budget could be based on a modeled attainment demonstration or, for areas with clean data (defined in the conformity rule as complete, quality-assured monitoring data demonstrating attainment in accordance with 40 CFR part 58), the SIP budget could be based on the motor vehicle emissions in the most recent year of clean data.

In addition to these options, moderate and above ozone nonattainment areas which EPA declares through rulemaking to be "clean data areas" under the May 10, 1995 policy could request that a budget based on the level of motor vehicle emissions in the most recent year of clean data be established through that EPA rulemaking process. See the May 10, 1995 memorandum cited above for more information about these types of areas.

B. Discussion of Comments and Rationale

1. Default Budgets for Clean Data Areas

Most commenters supported the proposed options for demonstrating conformity in areas that are not required to submit control strategy SIPs. However, some questioned the enforceability of a "default" budget for clean data areas because such a budget would be created through interagency consultation instead of the SIP process. Another commenter argued that state air quality agencies should not be allowed to create default budgets without EPA approval and public comment. The commenter believed that this would be the equivalent of adopting an element of the SIP, and it should be subject to the conformity rule's public participation requirements and approval by EPA.

After further consideration, EPA agrees that budgets must be established through rulemaking; an area cannot adopt a default budget without EPA review and public comment. As a result, if clean data areas choose to create a budget, the SIP process must be used (through which they could establish a budget based on clean data); or, if they are subject to the May 10, 1995 memo, they could establish a budget through the EPA rulemaking process described in the memo. Of course, clean data areas could also choose to use the emission reduction test flexibility already described above. Because both the SIP and rulemaking processes provide for EPA review and an opportunity for public comment, EPA believes that the commenters' concerns are addressed in the clean data option of this final rule.

EPA does not believe that areas choosing the rulemaking option will have any additional administrative burden in submitting clean data budgets for EPA review. Furthermore, since public comment is already a part of the rulemaking process, additional time will not be needed for gathering public input.

EPA recognizes there are clean data areas for which EPA has already completed rulemaking under the May 10, 1995, memorandum. If these areas are not subject to a control strategy SIP, they have the choice of using either the build/no-build or no-greater-than-1990 test, or the budget test if they decide to create one through the SIP process. Again, if such areas choose to submit a SIP budget, they have the option of basing the budget on a demonstration of clean data (rather than modeling) and the budget could be the motor vehicle emissions in the most recent year of clean data.

One commenter was concerned that, under the proposal, clean data areas would not have an incentive to submit maintenance plans for redesignation. EPA acknowledges the commenter's concern and believes that limiting the default budget option in today's final rule addresses this concern. However, EPA does believe that other significant incentives already exist for areas with clean data to submit maintenance plans.

Another commenter argued that the July 9, 1996, proposal was flawed because it would allow areas to adopt de facto budgets based on clean years even if subsequent years have NAAQS violations (thus demonstrating that budgets derived from clean data years are not adequate to maintain the standard). EPA believes that the final rule addresses this concern since any SIP budget would be established only through the rulemaking or SIP process. If an approved emissions budget is based on clean data and violations occur, EPA can issue a SIP call or, if a SIP has not yet been approved, EPA can declare the submitted budget inadequate during adequacy review. EPA also has the ability to disapprove a submitted SIP based on clean data if violations occur prior to approval.

2. Maintenance Areas

A few commenters believed that the proposed options for areas that are not required to submit control strategy SIPs should also be available to these areas during the maintenance period.

Since maintenance areas have already submitted SIP budgets and EPA has approved those budgets, maintenance areas must use the motor vehicle emissions budget(s) in their maintenance plans to demonstrate conformity unless a subsequent budget demonstrating maintenance is approved. As discussed in section III. of this preamble, "Other Comments on Conformity Tests," Clean Air Act section 176(c) specifically requires conformity findings to be based on approved SIPs. Maintenance plans that EPA has approved under Clean Air Act section 110 are enforceable and their budgets must be used for conformity.

3. Emission Reduction Test Flexibility in PM-10 and NO₂ Nonattainment Areas

One commenter requested that EPA remove the build/no-build test as an option for demonstrating conformity in PM-10 (particles with an aerodynamic diameter of less than or equal to a nominal 10 micrometers) and NO₂ (nitrogen dioxide) nonattainment areas that have not submitted control strategy SIPs or maintenance plans. Section

93.119(c) of the proposal, like the November 1993 final transportation conformity rule, offered PM-10 and NO₂ nonattainment areas the option to use either the build/no-build test or no-greater-than-1990 test to determine conformity, provided they have not submitted a control strategy SIP or maintenance plan. The commenter believed that the build/no-build test will not ensure that the frequency and severity of existing violations will not be increased, as required by Clean Air Act section 176(c)(1). Furthermore, commenters did not believe that the same logic that was used in the November 1993 final rule could be used to provide the build/no-build test option in ozone and CO nonattainment areas that are not required to submit control strategy SIPs.

Since the flexibility for PM-10 and NO₂ nonattainment areas was finalized in the November 24, 1993 conformity rule, the deadline for commenting on this provision has passed, and EPA is not obligated to respond to this comment. Nevertheless, EPA does believe that it is appropriate to continue to offer the build/no-build test as an option in PM-10 and NO₂ nonattainment areas. By ensuring that motor vehicle emissions are less than they would be if no new transportation investments were made, the build/no-build test does ensure that the frequency and severity of violations are not increased as a result of new transportation investments. EPA believes that this same rationale can be used to justify the build/no-build test option in ozone and CO areas that are not required to submit control strategy SIPs. In summary, EPA continues to believe that where no SIP has been submitted, the build/no-build test is sufficient for areas to meet the requirements of section 176(c)(1).

V. Rural Nonattainment and Maintenance Areas

A. Description of the Final Rule

In today's action, EPA finalizes the flexibility proposed in § 93.119, with two minor clarifications. Rural nonattainment and maintenance areas with submitted or approved control strategy SIPs or maintenance plans will be allowed to choose among several tests for demonstrating conformity for years after the time period addressed by the SIP: (1) the budget test; (2) the emissions reduction tests ("build/no-build test" and/or one of the 1990 tests, depending on what is required of the area's classification); or (3) air quality modeling.

In the proposal, EPA's third option was "air quality dispersion modeling," which was more specific than intended. The final rule's language has been changed to allow an area to use the air quality modeling technique it used in its SIP attainment or maintenance demonstration, even if that technique is not dispersion modeling. For example, some SIP attainment demonstrations (most commonly in PM-10 areas) are developed using rollback/rollforward techniques based on emission inventories, and/or chemical mass balance modeling, pursuant to EPA guidance. Where the SIP demonstration correctly used one of these techniques, the conformity determination can use the same technique. EPA will reject SIP budgets during the 45-day review period if such non-dispersion modeling was used inappropriately.

EPA also clarifies in the final rule that areas electing to use the emissions reduction tests to demonstrate conformity for the outyears must perform these tests even if the area has received a NO_x waiver.

Generally, NO_x waivers are findings by the EPA Administrator under Clean Air Act sections 182(b) or 182(f) that additional reductions of NO_x would not contribute to attainment of the ozone standard by the statutory deadline. Areas have historically applied for NO_x waivers to eliminate the NO_x emissions reduction requirement.

When EPA proposed to allow rural ozone areas with attainment demonstrations or maintenance plans to have the option of relying on the NO_x emissions reduction tests for the years not addressed by these SIPs, EPA did not intend to allow these areas the option of performing no NO_x test at all. This would be the result, however, if such areas could avoid meeting the substitute tests by receiving NO_x waivers. In the November 14, 1995, conformity amendments (60 FR 57183), EPA stated that areas with NO_x budgets have to conform to these budgets even if they were granted a NO_x waiver. EPA emphasized that "a NO_x waiver's demonstration that additional NO_x reductions would not contribute to attainment does not necessarily mean that NO_x increases would not affect an area's ability to attain and maintain the standard. The purpose of a NO_x budget is to prevent NO_x emissions from reaching levels that would threaten attainment or maintenance of the ozone standard."

EPA is allowing rural ozone areas to substitute the emissions reduction tests for the budget test as a means of demonstrating that these areas are meeting the requirements of Clean Air

Act section 176(c)(1) that plans, TIPs, and projects not cause or contribute to any new violation, worsen existing violations, or delay attainment of the NAAQS. Therefore, for the same reasons a NO_x waiver cannot exempt an area from the budget test, a NO_x waiver cannot exempt an area from the NO_x emission reduction tests when these tests are selected as a substitute for existing NO_x budgets. EPA believes that the clarification in the final rule is consistent with EPA's original intentions and stakeholders' understanding of the proposal, and therefore believes that a reproposal is not necessary to incorporate this minor change.

The choice of a test in rural areas will be determined through the interagency consultation process and will reflect the consensus of the state and local air and transportation agencies and the project sponsor.

B. Rationale and Response to Comments

Most commenters supported the proposal for increased flexibility in rural areas. EPA changed the language for the air quality modeling option because EPA agrees with the stakeholder who pointed out that modeling techniques deemed adequate in certain areas for SIP attainment demonstrations ought to be adequate in those areas for conformity determinations as well. EPA originally referred to air quality dispersion modeling because it is the technique generally required for SIP demonstrations. Because some PM-10 areas appropriately use air quality modeling that is not dispersion modeling, EPA has broadened its language to allow use of these other techniques.

One stakeholder commented that the proposal is illegal, because the Clean Air Act does not provide for an exemption from the budget test for rural areas. However, as explained in the proposal's preamble, EPA believes that providing some flexibility for the years not addressed by the SIP is consistent with the Clean Air Act. The Clean Air Act requirement for consistency with the SIP's emissions reduction goals can be construed to apply only for the years that an individual SIP revision addresses, where there is another appropriate method of demonstrating conformity as defined in Clean Air Act section 176(c)(1).

In general, EPA believes that a SIP budget, even if it is not yet approved by EPA, is a better measure of conformity than the build/no-build test. For this reason, EPA requires most areas to continue demonstrating conformity to

the SIP emissions budgets even after the timeframe of the SIP (see section VI., "Mismatch in SIP/Transportation Plan Timeframe," for more explanation). However, EPA believes it does have the flexibility to allow conformity to be demonstrated using some test other than the SIP budget for years not addressed by the SIP, if that test is more appropriate.

EPA believes that the reasons why the build/no-build test is less desirable than the budget test for most areas do not apply in the special circumstances of rural areas. The main critique of the build/no-build test is that the difference in emissions that it predicts is often small enough to be within the range of error of the models themselves. EPA believes this will not be as problematic in rural areas. Since there are fewer transportation projects and the transportation network is less complex in rural areas, the build/no-build test is more reliable. The test is better able to capture the effects of new projects in such areas. Therefore, EPA believes it is reasonable to allow the use of the build/no-build test as an option to demonstrate conformity for the time period of the transportation plan not covered by the SIP in rural areas.

Several commenters provided ideas for additional flexibilities in rural areas. One stakeholder suggested that areas should be able to use the budget from any year of clean data when employing the budget test. This suggestion is not being implemented today because SIP budgets must be established through notice-and-comment rulemaking. As stated in section IV. of this preamble, EPA believes that areas cannot adopt a default budget based on clean data without EPA review and public comment. See this section for more details on the options available for areas with clean data.

Another commenter suggested that areas be allowed to use alternatives to regional modeling, such as "subregional" modeling or "mesoscale analysis." EPA is not including that suggestion in this section because specific modeling requirements do not apply to rural areas; they only apply to urbanized areas with populations greater than 200,000. As a result, rural areas already have flexibility in modeling, provided that their methods consider all regionally significant projects in the nonattainment or maintenance area.

Several stakeholders suggested that the rule explicitly require state and local air agency concurrence for the selection of conformity tests, rather than just consultation. EPA does intend that

agencies reach agreement on which test to use to demonstrate conformity in a rural area. However, EPA is retaining the language of the proposal, because of concerns that requiring concurrence would imply that the existing conflict resolution process (by which state agencies can elevate disputes to the governor) cannot be used. EPA believes that the regulatory language adequately indicates that consensus should be reached or disputes raised through the conflict resolution process.

VI. Mismatch in SIP/Transportation Plan Timeframe

A. Description of Final Rule

This final rule retains the November 1993 conformity rule's requirements (described in the proposal as option 1). Conformity must continue to be demonstrated over a 20-year timeframe, and SIP budgets continue to apply for conformity purposes for all future years until superseded by other SIP revisions (except as provided in rural areas, as described above).

Although EPA is not changing the November 1993 conformity rule requirements with respect to the mismatch issue, EPA's existing SIP policy already does provide for some of the flexibility proposed in option 3, which would have allowed a default emissions budget to be established for years outside the maintenance plan's timeframe. Because EPA is aware of the challenges posed by the differing timeframes of the SIP and the transportation plan, EPA does allow SIPs to establish motor vehicle emissions budgets for conformity purposes for years outside the timeframe that the SIP normally addresses. For example, some areas are developing maintenance plans that include motor vehicle emissions budgets for conformity purposes for the years 2010 and 2015, even though the initial demonstration of maintenance is only required to address ten years. EPA's approval of these budgets is not an approval of a full 20-year maintenance demonstration; these budgets are for conformity purposes only and will be superseded when the second ten-year maintenance plan is submitted.

EPA will require areas to demonstrate that motor vehicle emissions budgets for years outside the timeframe of the maintenance plan are consistent with maintenance of air quality standards. EPA will not permit areas to simply use the motor vehicle emissions in the year of redesignation as a budget without considering growth in non-mobile source emissions, which was a

possibility discussed in the proposal under option 3. However, EPA believes it has the flexibility to approve budgets for years outside the usual maintenance plan timeframe for conformity purposes based on less rigorous demonstrations than are required for the Clean Air Act-mandated ten-year maintenance plan. Whereas normally control measures must be fully adopted in order for EPA to approve the SIP, EPA would be willing to approve conformity budgets that were based in part on enforceable commitments to adopt specific control measures in the future. Because these commitments would be included in the approved SIP, they would be enforceable by all parties, including the public. In addition, EPA would consider allowing the motor vehicle emissions budgets in the last year of the ten-year maintenance plan to be increased for future years provided offsetting emissions reductions are adopted or committed to in the SIP.

The ability to establish motor vehicle emissions budgets for conformity purposes for years outside the normal timeframe of the SIP is not specifically discussed in this final rule's regulatory text because it is currently possible under EPA's existing SIP policy, and therefore no regulatory changes are needed.

B. Rationale and Discussion of Comments

EPA is finalizing option 1 (i.e., not changing conformity rule requirements to address the mismatch in plan/SIP timeframes) for two reasons. First, EPA believes there are important benefits associated with this option, as commenters pointed out (discussed below). Second, EPA believes there are adequate flexibilities under the existing conformity rule and EPA SIP policy that will help areas address the challenges of the timeframe mismatch in a manner that is more supportive of air quality goals and prudent planning than any of the other options proposed. The other options proposed included option 2, which would have required emission reduction tests ("build/no-build test" and less-than-1990 test) for demonstrating conformity in years not addressed by SIPs; and option 3, which would have allowed a default motor vehicle emissions budget (such as the motor vehicle emissions in the year of redesignation) to be used for the years outside the maintenance plan's timeframe.

Many commenters supported option 1 because they believe that maintaining the SIP's emission targets for the timeframe of the transportation plan is a central purpose of conformity and

perhaps its most important requirement. Commenters stated that because the obligation to meet air quality standards persists indefinitely, the obligation to meet the motor vehicle emissions budget should not terminate after the attainment date or the last year of the maintenance plan. According to some commenters, it is appropriate to analyze the effects of transportation investments over a 20-year timeframe, because it may in fact take decades for these effects to be fully realized. They stated that it is better to use a long timeframe and make the right choices at the outset than to pursue a path for several years and then try to quickly overcome the adverse consequences of that path. One commenter pointed out that demonstrating conformity to the SIP's budget over the 20 years of the transportation plan is the best way to prepare for the fact that the benefits of fleet turnover do decline over time.

Some commenters preferred option 1 to the other options proposed because option 1 requires emissions related to growth to be specifically addressed and tradeoffs to be examined. According to these commenters, the other options would not accomplish this, and the conformity determinations that would result from these other options would not have as much integrity because they would not be based on a performance target with real meaning (i.e., a SIP budget that supports reasonable further progress, attainment, or maintenance).

Many other commenters supported option 3, which would have allowed a default motor vehicle emissions budget for the years after the last year of the maintenance plan. These commenters believe this option would be less burdensome than the other options. They also believe that SIP budgets may be unrealistic because they are not established with a 20-year horizon in mind, and therefore it is not necessarily appropriate to require areas to conform to them indefinitely. Option 3 was broadly discussed in the preamble to the proposal and included possibilities that ranged from allowing motor vehicle emissions to grow to levels in the year of redesignation without consideration of growth in non-mobile emissions, to allowing budgets to increase only if it is demonstrated that the standards will be maintained when growth in mobile, area, and stationary sources is considered. Several commenters supported option 3 only if the motor vehicle emissions budgets were based on a demonstration of maintenance that considered all emissions sources.

The approach that EPA is finalizing combines the benefits of option 1 with some of the flexibility contemplated by

option 3. EPA agrees with the commenters' reasons for supporting option 1. EPA is sympathetic to the concerns that prompted commenters to advocate option 3, but EPA believes that the flexibility allowed under existing SIP policy to establish reasonable budgets outside the timeframe of the SIP is an effective means of addressing those concerns without compromising the benefits of option 1. EPA is committed to assisting areas with the challenges that arise when addressing long-term emissions impacts. EPA also encourages a collaborative process between local, state, and federal agencies in order to facilitate acceptable solutions to these challenges under existing SIP policy.

A few commenters preferred option 2 (emission reduction tests) because in their specific areas they could pass the build/no-build test but not the NO_x budget test. However, some commenters opposed option 2 because the emission reduction tests have significant limitations and would not ensure that regional mobile source emissions remain consistent with attainment or maintenance requirements. One commenter stated that the build/no-build test is an imprecise analytical approach that bears no direct relationship to the attainment demonstration.

EPA agrees that these arguments against option 2 are compelling. Allowing areas to use emission reduction tests instead of SIP budgets would be inconsistent with EPA's action described in section II. to eliminate the emission reduction tests where SIP budgets have been established. Overwhelming support has been expressed for this elimination of the emission reduction tests in such cases, and this has convinced EPA that option 2 is not a suitable solution for addressing the mismatch of transportation plan and SIP timeframes. EPA is pursuing the approach proposed in option 2 only in the limited case of rural nonattainment and maintenance areas, for reasons specific to such areas as explained in section V.

C. Response to Specific Comments

Several commenters stated that EPA should allow areas to use any of the three proposed options. A commenter suggested that the choice of options would be decided by each area through its own interagency consultation process. As explained above, EPA believes that the option being finalized is the most appropriate. One commenter supported option 1 provided areas have more flexibility to account for future programs that will affect emissions. Currently, areas cannot assume future

programs unless they are adopted or included in the SIP. EPA believes that the approach being finalized today will allow the flexibility the commenter is seeking, because it allows budgets established for conformity purposes to be based on enforceable commitments in the SIP rather than requiring fully adopted control measures, as needed for approval as part of a control strategy SIP.

One commenter suggested that the plan should be qualitatively analyzed for the years beyond the timeframe of the SIP. EPA believes this would not be consistent with the Clean Air Act's requirement for the use of emissions estimates for determining conformity. In addition, EPA believes that both the air quality and transportation planning processes benefit from long-term quantitative analyses of transportation plans. EPA believes that areas have sufficient flexibility in analysis methods to develop a quantitative approach that is both reasonable and useful.

Some commenters suggested that conformity should not be required at all in years beyond the timeframe of the SIP. Other commenters suggested that conformity should not be required until there are tools adequate to the task. EPA believes this is not consistent with the Clean Air Act's requirement to demonstrate that the transportation plan will not cause or worsen violations of air quality standards. Conformity of a transportation plan cannot be determined unless all years of the transportation plan are considered. EPA believes that adequate analytical tools are currently available and are continually being improved. All areas have great freedom to improve their own analysis techniques, which EPA supports.

One commenter suggested that the options proposed for rural nonattainment and maintenance areas be provided for all areas as a way of addressing the mismatch in transportation plan and SIP timeframes. The options being provided to rural areas include a choice among the SIP emissions budget, the emission reduction tests, or air quality modeling. The emission reduction tests are not being pursued for all areas as described in the discussion of option 2, above. The reasons for using the emission reduction tests in rural areas, as described in section V., are only applicable in rural areas and would not provide a basis to use these tests in other areas. However, option 1 does give areas the opportunity to use either the SIP emissions budget or establish new budgets that are supported by air quality modeling.

Some commenters stated that demonstrating consistency with the motor vehicle emissions budget established for the attainment year or the last year of the maintenance plan is not sufficient to demonstrate that an activity will not cause or worsen air quality violations. These commenters argue that it must be demonstrated that the motor vehicle emissions budget is consistent with attainment or maintenance when the most recent projections about non-mobile source emissions growth are also considered. EPA does not believe that this is required by the Clean Air Act. EPA believes that if motor vehicle emissions are less than or equal to the most recent motor vehicle emissions budgets in the SIP that was approved as meeting attainment or maintenance requirements, then it can be stated that motor vehicles are not "causing or contributing" to violations, as required by the Clean Air Act. It is not the role of the conformity requirements to provide attainment or maintenance plans, but merely to prevent adverse impacts on such demonstrations.

However, EPA does recognize that consistency with the motor vehicle emissions budgets for the transportation plan's 20-year timeframe does not guarantee attainment or maintenance because of the possibility for growth in non-mobile sources. This is one reason why EPA is not finalizing a version of option 3 that would allow motor vehicle emissions to increase above approved SIP budgets without considering emissions from other sources.

VII. Non-Federal Projects

A. Description of Final Rule

As was proposed, the final rule allows certain regionally significant non-federal transportation 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. Non-federal projects are projects which 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) but which do not rely at all on any FHWA/FTA funding or approvals.

The final rule clarifies that only those non-federal projects from the first three years of the most recent conforming plan and TIP (or supporting regional emissions analysis) may proceed during a conformity lapse. In the proposal, EPA had simply stated that non-federal projects in the most recent conforming

plan and TIP's regional emissions analysis could proceed when a lapse occurs.

B. Rationale for Clarification and Response to Comments

Most commenters supported the proposal, and many said that it was appropriate because the emissions impacts from affected non-federal projects have already been considered and sufficient project reviews have already occurred. However, some commenters expressed concern that in their understanding the proposal would facilitate the exchanging of funds between federal and non-federal projects during a conformity lapse. Some even implied that there may be areas that would build large numbers of non-federal projects by exchanging funds, and thereby, avoid conformity consequences for an indefinite amount of time. There was concern that because some TIPs cover more than three years, sometimes even five or more years, a substantial number of non-federal projects could be built during a conformity lapse. Some of these commenters even believed that the proposal would allow areas to advance all non-federal projects in the 20-year transportation planning horizon during a conformity lapse, thus reducing or removing the incentive to develop transportation plans and TIPs that actually do conform. EPA did not intend this in the proposal, and as a result, EPA believes that a regulatory clarification is necessary in this final rule.

Although commenters suggested possible safeguards to protect against such abuses, including limiting the number of non-federal projects that could go forward during a lapse or restricting the ability to exchange funds between federal and non-federal projects, EPA believes that the final rule's clarification addresses these concerns.

EPA did not intend that a non-federal project identified for any year in the 20-year transportation planning horizon could proceed at any time. This interpretation would be inconsistent with other regulatory requirements and with the stated rationale for the proposed non-federal project flexibility. Under DOT's metropolitan planning requirements (23 CFR 450.332(c)), projects identified for funding in the first three years of the plan and TIP are the only projects that can proceed under any approved TIP. New TIPs are required every two years, and projects from the outyears of an approved TIP cannot be moved forward without a TIP amendment. Therefore, EPA believes that allowing non-federal projects in the

outyears of the TIP and plan to advance at any time for conformity purposes is inconsistent with this general regulatory context. In the proposal, EPA had intended that only those projects already scheduled to begin in the timeframe of the first three years of the TIP could proceed during a conformity lapse.

There are several reasons why the final rule's clarification is consistent with EPA's original intentions and rationale for providing areas flexibility for non-federal projects. During the development of the proposal, stakeholders who suggested the proposed non-federal project flexibility argued that it was appropriate because future plans and TIPs would have to consider the emissions from non-federal projects and offset them as necessary. These projects would ultimately have to be considered in the next TIP in the metropolitan planning process. In addition, as EPA pointed out in the preamble to the proposal and as many commenters argued, requiring non-federal projects to have been included in the most recent conforming plan and TIP ensures that the emissions consequences of the projects have been considered.

Neither of these rationales would be consistent with allowing a non-federal project from the outyears to proceed at any time. The emissions analysis for the plan and TIP would no longer be valid if the implementation dates of non-federal projects were altered. Allowing non-federal projects from the outyears to be accelerated during a conformity lapse so that a new conforming plan and TIP could be substantially delayed would in effect be allowing the non-federal projects to escape the scrutiny of the metropolitan planning process which EPA had relied on in making the proposal. The final rule's clarification ensures that the flexibility operates as originally intended by EPA and conformity stakeholders. EPA believes this is fully consistent with the original proposal and therefore does not require any reproposal prior to proceeding with final action.

C. Governor Approval

EPA requested comment on whether the governor should be required to approve each non-federal project that would proceed during a conformity lapse. EPA did not believe that it could propose such a change because governor approval is not explicitly required by the Clean Air Act, and it was unclear whether state and local officials should have the authority to adopt or approve non-federal projects during a lapse. Due to the comments received, EPA has

decided not to require governor approval in the final rule.

EPA received many comments on this issue that strongly supported the proposal to not require governor approval of non-federal projects affected by the final rule. Many reasons were cited by commenters. Some said that governor approval isn't necessary since the governor appoints the directors of the state transportation and air agencies, and in some cases, governors have even appointed the MPO as his/her designee for air quality planning. Others emphasized that the conformity rule already provides for involving the governor, when necessary, through the conflict resolution process. Many argued that local non-federal projects are usually time-sensitive and many local governments fund these projects in order to expeditiously move them through the planning process. In this case, requiring governor approval is unnecessary and would impede rather than facilitate the process of non-federal project implementation. Finally, some believed that it was not appropriate for governors to have authority over approving local non-federal projects. EPA agrees generally with commenters and believes that requiring governor approval is not necessary. Therefore, EPA is not requiring governor approval of non-federal projects during a conformity lapse.

D. Responses to Other Comments on Non-Federal Projects

EPA received other comments on the proposed non-federal project flexibility which did not result in changes to the proposal.

1. Comments Opposing Statutory Interpretation

One commenter argued that any exemption for non-federal projects would violate the statutory requirement that any such project only be approved or funded if it either "comes from a conforming plan and program," or its emissions when considered with those of "the conforming transportation plans and programs within the nonattainment area" do not exceed the applicable emissions budgets. The commenter argued that the present tense of the operative verbs in the statutory language does not allow exemptions for projects that come from a plan and program that no longer conform. The commenter also argued that this exemption cannot be justified as a grandfathering mechanism because it allegedly applies to projects that have not yet satisfied applicable federal requirements. Finally, the commenter objected that the proposal allows state DOTs to continue to build

projects with state funds during periods when the metropolitan transportation plans fail to satisfy the Clean Air Act's requirements for emission reductions, and therefore leads to a delay in attainment.

EPA believes that it is appropriate to allow non-federally funded projects that have previously satisfied conformity requirements to proceed during a conformity lapse because the existence of a conforming plan and TIP is not necessary to facilitate the implementation of such projects. As to the commenter's concern about potential emissions increases, any future plan and TIP will have to account for and offset if necessary the emissions of any non-federal projects that are implemented during a conformity lapse.

EPA acknowledges that there is some tension with the present tense statutory language concerning the existence of a conforming plan and TIP. However, EPA believes that this is a proper case of grandfathering projects that had been previously found to satisfy the applicable federal conformity requirements. The only obligation imposed by the conformity rule on non-federal projects is to account for project emissions in a conforming plan and TIP. If this has been done, EPA believes that it is appropriate to allow projects in the timeframe of the first three years of the plan and TIP to proceed towards implementation, so as not to interfere with the priorities of non-federal entities funding such projects.

2. Changes in Implementation Date

Another commenter said that it was unclear whether a non-federal project could go forward during a lapse if the project's design concept and scope had changed; or, if the project's implementation date had changed in a manner that changed emissions in a milestone or analysis year. Under the proposal and this final rule, a non-federal project cannot go forward during a conformity lapse if its design concept and scope has changed significantly. A non-federal project also cannot go forward if its implementation date changes in a manner that changes the emissions that the emissions analysis supporting the most recent conforming plan and TIP projected for a given analysis year. In either case, a new air quality analysis would be needed to ensure that the project would still conform, and it would be inappropriate to allow such projects to proceed based on the analysis in the most recent plan/TIP. The final rule's clarification should reduce confusion on this point.

3. Comments on Original Conformity Rule

One commenter objected to the provisions of the original conformity rule that do not require conformity determinations for non-federally funded projects. The commenter included detailed statutory arguments alleging that Clean Air Act section 176(c) on its face requires conformity determinations for all transportation projects, and the commenter also included citations to the legislative history supporting these allegations. The commenter also argued that non-federal project sponsors should provide a public process prior to determining that emissions from non-federal projects are consistent with applicable emissions budgets.

EPA's proposal did not cover this aspect of the conformity rule, which has been final since 1993. EPA did not intend to reopen the issue of whether non-federal projects should undergo conformity determinations when it proposed to allow certain non-federal projects to proceed during a lapse. As EPA explained in the preamble to the 1993 conformity rule, Clean Air Act section 176(c)(2)(C) clearly distinguishes non-federal projects from those projects required to conduct a conformity determination, requiring only that non-federal projects be considered in a regional emissions analysis prior to adoption or approval. Non-federal projects are not covered in the requirement to conduct a conformity determination in section 176(c)(1), which applies only to actions of federal agencies and metropolitan planning agencies. For these reasons, EPA is not responding in full to comments submitted on this issue. For more explanation of EPA's rationale for the provisions of the original conformity rule, see the preamble to the final rule at 58 FR 62188, 62204 (Nov. 24, 1993). Finally, since federal agencies do not approve non-federal projects, such approvals are not subject to the requirements of the federal Administrative Procedure Act. Non-federal project sponsors would have to comply with any applicable public participation processes required under state law.

VIII. Deadline for Use of Network Models and Affected Areas

A. Description of Final Rule

Today's action finalizes the proposal to require serious CO and serious, severe, and extreme ozone areas to use network models for conformity determinations by January 1, 1997. In addition, as proposed, these network modeling requirements are revised so

that they only apply to metropolitan planning areas with an urbanized area population over 200,000. EPA continues to believe that network modeling requirements are most important for large urbanized areas, and therefore believes that it is appropriate for the conformity rule to focus its specific modeling requirements on them. See section IX.A. for a description of the final rule's requirements for network models.

As stated in the proposal and required under the original conformity rule, whether or not an area is required to use a network model, all areas must use the consultation process to select regional models and assumptions, as required by § 93.105(c).

B. Rationale and Discussion of Comments

Most commenters supported the final rule's limiting of network modeling requirements to serious and above areas with an urbanized population over 200,000. Commenters agreed with EPA that network modeling is not always appropriate in rural or urban areas with smaller populations, and therefore, should not be required in these areas.

One commenter suggested that all urban areas with a population greater than 50,000 people should also be required to use network models because these models are simple and inexpensive. However, the commenter did not believe that the proposal would seriously weaken the conformity process, since most of these smaller cities already use network models for conformity analyses.

As previously stated, EPA believes that network modeling requirements are most important for large urbanized areas. As a result, EPA is not changing the proposed population threshold. However, EPA also notes that § 93.122(c) of the conformity rule requires areas that are already using network models to continue using them, even if they are not serious or above areas or have a population less than 200,000. EPA and DOT will consider the specific technical needs of smaller areas when developing future modeling guidance.

A couple of commenters supported stratifying the network modeling requirements by size of urban area. EPA believes that the final rule in part addresses this concern by only requiring larger urbanized areas to adhere to the network modeling requirements. However, EPA does not want to create a complicated stratification system that would require multiple sets of modeling requirements. Therefore, EPA did not

change the rule in response to this comment.

As proposed, today's action also extends the deadline for implementing the network modeling requirements from January 1, 1995, to January 1, 1997. A few commenters suggested that MPOs that are not meeting the rule's network modeling requirements should be put on a timetable for compliance. Other commenters thought that extending the deadline was unnecessary due to the ease of implementing such a network model, especially since the majority of areas already have a network model in place. They also felt that an extension would seriously weaken the modeling regulation. Some commenters stated that the extension of the deadline is obsolete, since the final rule would be published after January 1, 1997.

EPA acknowledges that the January 1, 1997, deadline has already passed. The original conformity rule required that areas use network models in conformity analyses by January 1, 1995, and when the proposal was being developed, most areas had achieved the rule's network modeling requirements by this deadline. However, as discussed in the proposal, a few areas had not yet complied with the deadline, and EPA believed that an extension until January 1, 1997, would be adequate to address their difficulties.

EPA did consider extending the deadline even further when it became apparent that the final rule would not be effective before January 1, 1997. However, reproposal would have been necessary to significantly extend the proposed January 1, 1997, deadline, and EPA believes it is likely that the few areas in question will have adequate network models developed before a reproposal could be finalized.

For all of these reasons, EPA is retaining the January 1, 1997, deadline. EPA agrees with the commenters that the majority of affected areas are already using network models. EPA and DOT are currently working with the two areas that have not yet met the network modeling requirements so that they will overcome their unique circumstances and meet the requirements in the future.

IX. Content of Network Modeling Requirements in Serious and Above Ozone and CO Areas

A. Description of Final Rule

In today's final rule, EPA is streamlining the conformity rule's modeling requirements and committing to collaborate with DOT to develop future modeling guidance. Specifically, EPA is eliminating several modeling criteria from regulatory text while

retaining those criteria that establish minimum acceptable practice.

The proposal requested comment on three options for addressing the modeling criteria in the conformity rule. Option 1 proposed to eliminate all of the 11 required attributes of network models in the original November 24, 1993, final transportation conformity rule and address the attributes only in guidance. Option 2 would have retained all of the original modeling attributes. Option 3 proposed to streamline the original requirements for network models and address the eliminated attributes in guidance. Today's action finalizes option 3 with some minor modifications.

The final rule includes six required elements for network modeling in serious and above ozone and CO areas with an urbanized population over 200,000. These elements include the five that were proposed as option 3 (with minor wording changes), as well as the November 1993 conformity rule's requirement in § 51.452(b)(1)(iv)/§ 93.130(b)(1)(iv) for reasonable agreement between zone-to-zone travel times used in trip distribution and the travel times resulting from traffic assignment.

Specifically, this final rule requires network-based models to be validated against observed counts (peak and off-peak, if possible) for a base year that is not more than ten years prior to the date of the conformity determination. Model forecasts must be analyzed for reasonableness and compared to historical trends and other factors, and the results must be documented. Land use, population, employment, and other network-based model assumptions must be documented and based on the best available information. Scenarios of land development and use must be consistent with the future transportation system alternatives for which emissions are being estimated. The distribution of employment and residences for different transportation options must be reasonable.

A capacity-restrained traffic assignment methodology must be used, and emissions estimates must be based on a methodology which differentiates between peak and off-peak volumes and speeds, and which uses speeds based on final assigned volumes. Zone-to-zone travel impedances used to distribute trips between origin and destination pairs must be in reasonable agreement with the travel times that are estimated from final assigned traffic volumes. Where use of transit currently is anticipated to be a significant factor in satisfying transportation demand, these times should also be used for modeling

mode splits. Finally, network-based models must be reasonably sensitive to changes in the time(s), cost(s), and other factors affecting travel choices.

EPA believes that the streamlined criteria and clarified rule language will assist areas in implementing the rule's network modeling provisions. The final rule does not create any new network modeling requirements for large, urbanized serious and above ozone and CO areas.

As stated in the proposal, EPA and DOT will develop modeling guidance in the future to address some of the modeling requirements that were eliminated from the final rule and to foster the exchange of information on current and future modeling improvements. As discussed later in this section, EPA and DOT are committed to an open stakeholder process about modeling procedures that will begin shortly after the rule becomes effective.

B. Rationale and Discussion of Comments: Selected Option

There were commenters who supported each of the three proposed options for the content of the network modeling requirements. Some supported option 1 because they believed that eliminating all modeling attributes would simplify the conformity rule and create maximum flexibility for areas. Other commenters argued strongly for option 2, which would have retained all 11 modeling attributes from the original rule. According to one commenter, removing all of the modeling attributes from the rule would have detrimental effects on the entire conformity process. Finally, many commenters from the transportation and environmental communities supported option 3, which proposed to streamline the modeling requirements without fully eliminating them. These commenters believed that having some baseline modeling criteria in the rule ensures national consistency of network models while streamlining the rule to allow for flexibility at the state and local levels.

As previously stated, this final rule streamlines the original conformity rule's network modeling criteria by eliminating some criteria and clarifying the rule's language. EPA is retaining some modeling requirements in this final rule because EPA agrees with commenters that minimum modeling standards are an important component of the conformity process. Many commenters believed that all or some of the original modeling criteria should be retained in the final rule, because without them, modeling practice would

become highly variable across the country. They also thought that eliminating all criteria would undermine the integrity, reliability, and credibility of the process for assessing the expected impacts of transportation investments on travel demand, travel behavior, and estimates of future vehicle miles traveled (VMT) and emissions. Others believed that having modeling criteria in the conformity rule has spurred the funding and development of state and local transportation model improvements. Finally, some pointed out that sound network models are needed for other processes besides conformity, such as SIP development, and therefore should be retained.

Other commenters were concerned that lawsuits would increase if all of the modeling attributes were eliminated, due to the inconsistency of requirements across the country. According to commenters, the outcomes of these suits would be hard to predict and money would be wasted in the adversarial process.

EPA agrees with these comments and believes that the final rule addresses them. EPA also agrees that nationally consistent and enforceable minimum standards are central to the integrity of the conformity process. Minimum standards clarify the expectations of all agencies involved in the conformity process and thus ensure some equity among all areas.

One commenter argued that EPA cannot eliminate all of the modeling attributes because they are a regulatory requirement which cannot be substituted with unspecified guidance that is developed outside of the rulemaking process. EPA agrees with this comment and is addressing it by retaining minimum standards in this final rule.

Although some commenters supported option 1, EPA does not believe that eliminating the modeling requirements is necessary to achieve the objectives of these particular commenters. Some supported option 1 because eliminating all modeling criteria would allow areas to tailor their network models to satisfy their current modeling and air quality planning needs. According to one commenter, this option would distribute resources and technical expertise appropriately in state and local agencies. Commenters also believed that under option 1 areas would be able to do sound quantitative analysis while having the flexibility to accommodate modeling improvements and demographic changes in their area. A couple of commenters suggested states should have the authority to determine network model attributes on

an area-by-area basis, and one approach for this is to allow state-level approval of an area's model subject to the interagency consultation process.

EPA believes that areas have the flexibility to appropriately tailor their models and distribute their resources under option 3 as well as option 1. The conformity rule's modeling requirements define minimum acceptable practice, and beyond this, areas have flexibility to determine appropriate modeling practices and accommodate modeling improvements through interagency consultation. EPA does not believe that areas should be able to use models that do not meet minimum standards of acceptable professional practice, for the reasons described in this section.

One commenter stated that the criteria in options 2 and 3 are accounted for in some way in existing practice, and that requiring them does not advance the state of the practice and may hinder it if future developments lead to improved, but different, methodologies. Another commenter suggested that by eliminating all modeling criteria, EPA and DOT could incorporate future modeling improvements by revising the guidance rather than having to go through the difficult and time-consuming process of revising the rule. Others believed option 1 would give agencies across the country access to technical changes and expertise which may not be available to them on a case-by-case basis, and may provide a better way of communicating updates and improvements in network modeling procedures.

EPA does not believe that establishing baseline modeling criteria, as is being done in this final rule, will inhibit the adoption of future modeling improvements. EPA agrees that future modeling guidance should provide information to state and local agencies about modeling updates, and EPA and DOT are committed to working with stakeholders to exchange ideas in the guidance development process. However, EPA does not believe it is necessary to eliminate the rule's modeling requirements in order to issue future modeling guidance. As general modeling practices improve, EPA and DOT will make periodic updates in the form of non-enforceable modeling guidance, rather than future amendments to the conformity rule.

An area that has not yet implemented the currently required model improvements supported option 1 because the area believed option 1 would provide flexibility and make a conformity lapse for this area less likely. EPA believes that it would be

inappropriate to eliminate all of the modeling criteria just because a few areas are having temporary difficulty achieving them. This stakeholder concern was also raised in the context of extending the deadline for implementing network modeling requirements. EPA considered the merits of this comment, and as outlined above, decided that a reproposal to extend the deadline could not be completed in time to provide relief to the few affected areas. As previously mentioned, EPA and DOT are assisting the two areas without adequate network models to achieve the minimum standards in this rule.

EPA believes that option 3 also addresses the concerns of the commenters who supported option 2. These commenters seemed most concerned with whether any modeling requirements would be retained in the rule; option 1 would have eliminated all of the rule's network modeling requirements. Many of the commenters who supported option 2 also supported option 3, provided there were modifications for some of the language in option 3. EPA believes that the changes made to option 3, which are discussed below, make the final rule's language more streamlined, clear, and useful than the 1993 conformity rule language proposed for retention in option 2.

A few commenters who supported option 3 also thought that areas should not be required to use network modeling improvements in the conformity process prior to their application in the SIP process. The commenters believed this would remedy problems associated with inconsistencies between the models used in conformity analysis and those used in SIP development. EPA recognizes the commenters' concerns about the implementation difficulties that may occur as a result of model improvements. However, Clean Air Act section 176(c)(1)(B)(iii) requires conformity determinations to "be based on the most recent estimates of emissions." EPA believes that areas must use the most current tools available at the time of the conformity determination, in accordance with the Clean Air Act. Using the best models and assumptions will also produce the best emissions estimates on which areas will base decisions regarding transportation and air quality. EPA also notes that areas already have the ability to use the consultation process to coordinate the introduction of transportation modeling improvements into their planning processes. For these reasons, EPA is not finalizing the commenters' suggestion.

C. Future Modeling Guidance and Response to Comments

As stated in the proposal, EPA and DOT will develop modeling guidance in the future. This guidance will address some of the modeling requirements that were eliminated from the final rule; provide guidance on implementing modeling requirements; and facilitate the exchange of information on advancements in modeling. EPA and DOT are committed to working with stakeholders in the development of the guidance, an idea which was supported by many commenters. This process will begin soon after this rule becomes effective, and will include stakeholder participation in workshops for developing the guidance. In addition, EPA and DOT will make drafts available for stakeholder comments. This joint federal, state, and local effort will bring together the expertise to assure national consistency and meaningful emissions results in conformity analyses.

Some commenters were concerned that the guidance would be mandatory and that future guidance updates would be difficult to implement if it were mandatory. Today, EPA clarifies that the guidance will not be an enforceable requirement, although EPA and DOT encourage use of future guidance on a voluntary basis as deemed appropriate by affected state and local agencies. There is also no specific date by which future modeling guidance must be used, or by which models are required to be improved in accordance with future guidance, since the use of future guidance is not an enforceable requirement. Areas will decide upon how to implement modeling guidance using the interagency consultation process.

Another commenter said that each MPO should have the responsibility to demonstrate the adequacy of their model through documentation, and such documentation should be included as an appendix to the area's conformity package. EPA agrees with this comment and encourages MPOs to submit such documentation with their conformity determinations.

D. Rationale and Discussion of Comments: Specific Criteria

As discussed above, this final rule specifies six requirements for network models for serious and above ozone and CO areas. These replace the 11 that were required by the November 1993 conformity rule. This final rule includes the five requirements that were proposed as option 3, as well as a requirement from the November 1993 conformity rule that was not originally

proposed as part of option 3 (but was included in proposed option 2, which included all requirements of the 1993 rule). Several minor changes were made to the wording proposed in option 3 in order to respond to comments, reduce ambiguity, and streamline the text.

EPA proposed to require network-based models to be validated against peak and off-peak ground counts for a base year that is not more than ten years prior to the date of the conformity determination. The final rule requires validation against "observed" counts rather than "ground" counts because the term "ground" counts sometimes implies automobile counts only. In fact, models should be validated against counts for all modes, including transit, bicycle, and pedestrian. EPA believes that because "observed" counts is a more general term, it more appropriately conveys the intent of the proposed requirement.

EPA has also qualified the proposed requirement for validation against peak and off-peak counts so that validation against both peak and off-peak counts is only required where it is possible. The November 1993 conformity rule simply required validation against ground counts; there was no reference to peak and off-peak. When EPA proposed option 3, it did not intend to impose any new or more stringent network modeling requirements. Since the time of the proposal EPA has become aware that not all areas collect peak and off-peak counts. As a result, although EPA continues to believe that validation against peak and off-peak counts is preferable, the rule only requires it where it is already possible given available data.

A commenter suggested that the conformity rule should require areas to validate their models for a second year at least three years before or after the base year whenever possible. The commenter also suggested that the rule require validation against peak and off-peak travel demand, traffic volume, speed, and mode share data for household and commercial travel. EPA did not incorporate these suggestions in the conformity rule because the modeling requirements are only intended to outline minimum practice, and in addition, EPA intends for these amendments to streamline the existing rule. The EPA/DOT modeling guidance will have further discussion about best practices and other advances in validation techniques, and EPA believes that this will be a better forum to address the commenter's ideas.

This final rule adds to the proposed validation requirement a sentence specifying that model forecasts must be

analyzed for reasonableness and compared to historical trends and other factors, and that the results must be documented. This sentence was added for several reasons. First, a commenter suggested that the conformity rule should require model forecasts to be compared to documented historical trends in travel behavior, such as changes in per capita vehicle trips and VMT, trip length, mode shares, and time-of-day-travel, and require significant differences between trends and forecasts to be explained. EPA agrees that this is minimum acceptable practice and has added language to the conformity rule accordingly. The language that is included in the final rule is more general than that suggested by the commenter, and EPA plans for the EPA/DOT modeling guidance to address the issue in more detail. EPA also added this language because it better reflects what EPA intended when it proposed that network-based modeling inputs (such as land use, population, and employment) be appropriate to the validation base year. This language is consistent with the proposal on this issue and does not require reproposal prior to final action.

The second network modeling requirement in the final rule requires land use, population, employment, and other network-based model assumptions to be documented and based on the best available information. The proposal's requirement for these assumptions to be "appropriate to the validation base year" has been eliminated in favor of the new language described above that requires reasonableness checks as part of validation. A commenter suggested that the proposed requirement be expanded to refer not only to land use, population, and employment assumptions, but also demographic and spatial attribute assumptions. EPA believes that the final rule's reference to "other network-based modeling inputs" is sufficiently inclusive, and specificity such as the commenter suggests is more appropriate to the EPA/DOT modeling guidance.

The final rule's third network modeling requirement states that scenarios of land development and use must be consistent with the future transportation system alternatives for which emissions are being estimated. This is substantially similar to the language proposed as the fourth modeling requirement in option 3, with minor wording adjustments for the sake of clarity. The final rule also includes a sentence stating that the distribution of employment and residences for different transportation options must be reasonable. This statement is intended

as further clarification of what was intended by the original proposed language. Appropriate consideration must be given to how major anticipated transportation system improvements might influence development and, in turn, how that might affect the forecasted distribution of population and employment used to estimate travel and emissions.

A commenter suggested that instead of the proposed language, EPA should require that areas make reasonable adjustments to land use assumptions between scenarios to account for effects of changes in accessibility on the likely timing and pattern of development, using the best methods available. EPA does not believe it is appropriate for the conformity rule to specifically require the use of the "best" methods, because cutting-edge practices may not be reasonably available at the same time in all areas subject to conformity's network modeling requirements. With this exception, EPA believes that the commenter's suggestion is basically a restatement of the language that is being finalized.

The final rule's fourth network modeling requirement states that a capacity-sensitive assignment methodology must be used. In addition, emission estimates must be based on a methodology which differentiates between peak and off-peak link volumes and speeds and uses speeds based on final assigned volumes. This additional language clarifies the proposed requirement that "peak and off-peak travel demand and travel times must be provided," which did not indicate which step in the modeling process was being referred to. EPA in fact simply intends that emissions be calculated on the basis of peak and off-peak speeds separately and applied to peak and off-peak final assigned volumes, regardless of whether these assigned volumes are based on peak and off-peak modeling or are modeled on a 24-hour basis.

The final rule's fifth network modeling requirement is based on § 51.452(b)(1)(iv)/§ 93.130(b)(1)(iv) of the November 1993 conformity rule, which requires feedback of travel times resulting from traffic assignment to travel times used in trip distribution. Although this requirement was not proposed as part of option 3, EPA received comments based on proposed option 2 that this requirement of the original rule should be retained. Commenters pointed out that this type of consistency in the evaluation of travel time is almost universally recognized to be scientifically valid. A commenter stated that not requiring feedback would allow analyses to be manipulated to

produce desired results. Another commenter stated that most MPOs have already implemented full feedback, and it is easy to perform and more accurate than partial feedback. Commenters submitted technical reports and papers to the docket in order to document their claims that full feedback is recognized to be a necessary and sound modeling improvement.

EPA agrees with commenters that there is clear theoretical justification for feedback between traffic assignment and trip distribution, and that feedback may be essential to accurate forecasts when congestion exists. In addition, EPA agrees that full feedback is already widely available and used. As a result, EPA believes it is appropriate to retain the feedback requirement.

The regulatory language has been slightly modified from the November 1993 rule to read that zone-to-zone travel impedances used in trip distribution must be in reasonable agreement with travel times that are estimated from final assigned traffic volumes. The language now refers to "impedances" rather than "travel times" because trip distribution impedances may reflect more than just vehicle travel time (e.g., cost, travel times by other modes, etc.). The language refers to travel times "estimated from final assigned traffic volumes" rather than travel times "which result from" traffic assignment in order to reflect the fact that speeds should be estimated by post-processing assigned volumes.

The final rule's sixth and final network modeling requirement is for network-based models to be reasonably sensitive to changes in the time(s), cost(s), and other factors affecting travel choices. EPA's proposed option 3 would have required models to 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 has eliminated the reference to "trip-making changes" because EPA received comments indicating that this implies a requirement for trip generation to be dependent on accessibility. This is not what EPA intended. The November 1993 conformity rule strongly encouraged a dependence of trip generation on the accessibility of destinations, but it was not specifically required. EPA continues to believe that such a trip generation requirement is not widely available, minimum practice. In addition to deleting "trip-making changes," EPA made other modifications to the proposed requirement in order to streamline the

language. By making the language more general, EPA believes that the qualification "if the necessary information is available" is no longer necessary. EPA has therefore eliminated this language.

EPA received comment that § 51.452(b)(1)(v)/§ 93.130(b)(1)(v) of the November 1993 conformity rule should be retained in addition to the other paragraphs proposed as option 3. Section 51.452(b)(1)(v)/§ 93.130(b)(1)(v) of the November 1993 conformity rule required free-flow speeds on network links to be based on empirical observations. EPA is not including this requirement in the final rule because it has been widely misinterpreted, and because issues relating to the use of speeds in network models are complex enough that they are best handled in modeling guidance, where they can be fully discussed. The November 1993 requirement was read by some to require significant data collection efforts. In fact, EPA had simply intended that available empirical information be used instead of posted speed limits. In addition to creating this misinterpretation, the original language was not clear about which step of the modeling process it referred to, and whether it was directed at input assumptions or outputs.

EPA believes that this issue warrants a full discussion in the EPA/DOT modeling guidance, and that the original regulatory requirement regarding free-flow speeds should be eliminated from the streamlined rule in order to avoid confusion. However, EPA and DOT would like to emphasize that input network speed assumptions used in model application must be consistent with speed assumptions used in model development and calibration, and that these assumptions and calibration techniques should be documented. EPA and DOT recognize that free-flow impedance inputs into traffic assignment may not reflect empirically observed free-flow speeds, because these input impedances may reflect considerations that affect travel behavior other than travel time, such as driver preferences for using specific classes of facilities. If free-flow impedance inputs used in traffic assignment deviate significantly from observed free-flow speeds, the documentation should include a discussion of the differences and rationale for adjustments made.

In addition, since emissions estimates are extremely sensitive to vehicle speed, EPA and DOT recommend that speeds be estimated in a separate step after traffic assignment (also known as "post-processing"), using refined speed-

volume relationships and final assigned traffic volumes. Post-processed speeds estimated in the validation year should be compared with speeds empirically observed during the peak and off-peak periods. These comparisons may be made for typical facilities, for example, by facility class/area type category. Based on these comparisons, speed-volume relationships used for speed post-processing should be adjusted to obtain reasonable agreement with observed speeds. Regardless of the specific analytical technique, every effort must be made to ensure that speed estimates are credible and based on a reproducible and logical analytical procedure.

X. Adding Non-Exempt Projects to the Plan/TIP Without Regional Analysis

A. Description of Final Rule

In today's final rule, EPA is not finalizing the flexibility proposed in § 93.122(b)(4), which would have allowed projects to be added to the plan and TIP based on an alternate emissions analysis that does not use network modeling (for areas that are required to use network models, i.e., serious and above areas with an urbanized population over 200,000). This final rule retains the 1993 conformity rule requirement that every plan/TIP amendment that involves regionally significant, non-exempt projects requires the same level of regional emissions analysis. For the purposes of this discussion, a non-exempt project is any transportation project other than those listed in § 93.126, "Exempt projects," and § 93.127, "Projects exempt from regional emissions analysis."

Areas that are not serious or above or do not have an urbanized population over 200,000 are not affected by the proposal or this change to the proposal, because they are not subject to requirements for network models.

B. Rationale

Based on stakeholder comments received, EPA has determined that the flexibility to add projects without a regional emissions analysis would have to be accompanied by safeguards or limitations that were not proposed. EPA believes that the restrictions that would have to be imposed on the flexibility would outweigh its benefits.

EPA agrees with a commenter who pointed out that regulatory requirements that govern how satisfaction of a conformity test is demonstrated cannot be removed and replaced with unspecified guidance that is not subject to notice and comment. EPA believes

that the commenter is correct in asserting that guidelines for how the alternate emissions analysis would have to be performed would have to be included in regulatory language, if the flexibility were to be finalized. Such additional regulatory language would require reproposal because it is a significant departure from what was originally proposed; EPA did not propose any specific guidelines or limitations for this flexibility in either the preamble or regulatory language of the July 9, 1996, proposal.

Other commenters expressed serious concerns that the flexibility to add projects without analysis could undermine the coordinated planning process and achievement of air quality objectives unless some safeguards are included. Suggestions for limitations and safeguards included adding minimum criteria for alternate analysis methodology in the rule; limiting the flexibility to projects which are unlikely to cause major long-term changes in travel and development patterns; limiting the flexibility to a certain number of projects per planning cycle; or requiring that the emissions from the existing plan and TIP be below a minimum threshold of the applicable emissions budget. Commenters were also concerned that safeguards needed to be applied consistently throughout the country. Including such safeguards would require reproposal, and could result in additional rule complexity that would hamper use of the proposed flexibility.

Because EPA believes it is legally compelled to include minimum guidelines for alternate emissions analysis in the regulatory text, EPA's choice was to either repropose regulatory guidelines and safeguards or eliminate the proposed flexibility. EPA is choosing the latter in today's final rule because the few alternate methodologies suggested by commenters were not sufficient to provide a basis for EPA to propose general regulatory guidelines. In addition, EPA believes that additional regulatory text would outweigh the benefits of the flexibility.

The few methodologies proposed by stakeholders were not sufficient to form the basis of nationally applicable, minimum guidelines for alternate emissions analysis. When EPA proposed the flexibility, it was seeking a procedure that would yield similar results as a full-scale regional analysis but with less effort. However, the methodologies suggested by commenters were sketch planning techniques, which are ancillary to but not substitutes for network modeling.

While sketch planning techniques may be appropriate for certain projects in certain circumstances, the commenters did not suggest guidelines that would delineate when sketch planning techniques may be an adequate approximation or how these techniques could be replicated nationally.

Based on comments received during the development of the proposal and during the comment period on the proposal itself, EPA and DOT believe that regulatory constraints on the proposed flexibility would defeat the flexibility's purpose. Many commenters did not believe EPA could or should develop alternate analysis techniques that would apply nationally, because the value of the flexibility would be its application on a case-by-case basis. In addition, many stakeholders want the regulatory text to be streamlined and procedural modeling guidelines to be minimized.

EPA and DOT also believe that the possible benefits of the proposed flexibility do not warrant the complication of a new set of modeling guidelines. Commenters have indicated that the proposed flexibility would not have a large impact on day-to-day implementation of the conformity rule. Many commenters stated that the flexibility would be used infrequently, or only in limited circumstances. Some commenters believe that a full-scale regional analysis is just as easy as using an alternate sketch planning method. For example, a commenter indicated that adding a project and running the regional model again is not time-consuming once the network for the plan has already been coded. EPA and DOT believe the time and effort spent in developing an alternate procedure and getting agreement from all involved agencies seems greater than that involved in running the regional model.

C. Pilot Program

Although EPA did not grant the general analysis flexibility in today's final rule, EPA and DOT remain willing to consider alternate procedures on a case-by-case basis for determining the impact of transportation projects, since a substitute may prove to be more expeditious and less costly in certain circumstances than a network-based analysis. Those areas that develop such an alternate procedure are invited to apply to the conformity pilot program, proposed on July 9, 1996. Given the pilot program's purposes to allow greater flexibility in implementing the rule and to evaluate potential improvements to the rule, the pilot program is an appropriate vehicle for this flexibility.

XI. Consequences of SIP Disapproval**A. Description of the Rule**

EPA is finalizing the primary option in the proposal, which is the option for which the regulatory text was proposed. In today's final rule, EPA is also clarifying the definition of a protective finding. Consequences of SIP disapproval apply when control strategy SIPs are disapproved. Control strategy SIPs are 15% SIPs, post-1996 SIPs, and attainment demonstrations.

1. Disapproval With a Protective Finding

When disapproving a control strategy SIP revision, EPA may give the SIP a protective finding. If EPA disapproves a SIP but gives a protective finding, the motor vehicle emissions budget in the disapproved SIP could still be used to demonstrate conformity. There would be no adverse conformity consequences unless highway sanctions were imposed, as is the case with respect to all other SIP planning failures. Highway sanctions would be imposed two years following EPA's disapproval if the SIP deficiency had not been remedied. The conformity of the plan and TIP would lapse once highway sanctions were imposed.

EPA would give a protective finding where a submitted SIP contains adopted control measures or written commitments to adopt enforceable control measures that fully satisfy the emissions reductions requirements relevant to the statutory provision for which the SIP was submitted, such as reasonable further progress (RFP) or attainment. That is, EPA would give such a submitted SIP a protective finding if it contains enough emissions reduction measures or commitments to these measures to achieve its purpose of either demonstrating RFP or attainment. Like the November 1993 rule, a SIP could receive a protective finding even if all control measures are not fully adopted in enforceable form, provided there are written commitments to such measures. EPA would not give a protective finding to a SIP whose emission reduction measures or commitments are inadequate to achieve the required RFP or attainment.

2. Disapproval Without a Protective Finding

In the cases where EPA disapproves a SIP and does not give it a protective finding, an area has a 120-day grace period, after which the only transportation projects that could be found to conform would be those included in the first three years of the currently conforming transportation plan and TIP. No new plans, TIPs, or

plan/TIP amendments could be found to conform after the grace period. Further, no additional projects not already in the first three years of the currently conforming plan and TIP could be found to conform. Since exempt projects and non-federal projects do not require conformity determinations, they could proceed as long as they meet other applicable requirements of the conformity rule (for example, a regionally significant non-federal project must have been included in the regional emissions analysis supporting the most recent plan and TIP conformity determination).

If any one phase of a project is included in the first three years of the currently conforming plan/TIP, all subsequent phases could proceed following a disapproval, provided that all phases of the project were included in the plan/TIP conformity analysis and all other applicable project-level conformity criteria were satisfied (e.g., hot-spot requirements).

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 budget inadequate. If such a replacement SIP does not apply for conformity purposes 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 plan and TIP. The lapse would last until a replacement SIP applies for conformity purposes (i.e., until an adequate replacement SIP has been submitted to EPA).

During the 120-day grace period, plans, TIPs, and projects could be found to conform using the budgets from the disapproved SIP, if there is no applicable replacement SIP for transportation conformity purposes. This 120-day grace period is intended to allow areas to complete conformity determinations that were in progress at the time of EPA's final disapproval. Both the MPO and DOT must have determined conformity by the end of the 120-day grace period.

As in the previous conformity rule, adverse consequences would occur following any EPA final disapproval action on a control strategy SIP without a protective finding, even if the disapproval is limited or partial. The motor vehicle emissions budget is sufficient for conformity determinations only if the SIP as a whole satisfies the Clean Air Act requirements for RFP or attainment. 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 RFP or attainment, and it is not possible to determine whether consistency with the motor vehicle emissions budget will result in a level of emissions consistent with RFP or attainment.

A plan/TIP conformity lapse previously imposed under the November 1993 rule due to SIP disapproval without a protective finding would convert to a "freeze" as described in this notice once this rule becomes effective, provided highway sanctions have not yet been imposed. The "freeze" would continue until highway sanctions are imposed, which normally occurs two years after EPA's final disapproval. Once highway sanctions are imposed, the conformity of the plan and TIP would lapse, as occurs whether or not the SIP had received a protective finding.

Finally, EPA wishes to clarify that although the preamble to the proposal inadvertently indicated that consequences of SIP disapproval also apply to disapproval of maintenance plans, this is not what EPA intends nor is it included in the final rule language. Consequences of SIP disapproval only apply when control strategy SIPs are disapproved. EPA did not refer to maintenance plans in the relevant regulatory text of the proposal or the conformity rule as amended in 1995. The regulatory text would not make sense with respect to maintenance plans because sanctions do not apply for maintenance plan disapprovals. Furthermore, there is less need to apply the consequences for disapproving a maintenance plan, since an area could revert to using its attainment SIP budget for demonstrating conformity if a maintenance plan is disapproved.

B. Rationale

EPA believes that the option finalized today provides the best balance between the competing objectives of minimizing new transportation commitments after a SIP disapproval and minimizing disruption to the transportation planning process. EPA believes that new projects should not be approved when the control strategy SIP has been disapproved without a protective finding, because if a SIP does not identify enough emission reductions and the motor vehicle emissions budget does not provide for RFP or attainment, then there is no basis to claim that a transportation activity conforms within the meaning of Clean Air Act section 176(c). Furthermore, adding more transportation projects may make it

more difficult for the air agency to create a SIP that achieves sufficient emissions reductions, and may intensify the need for additional control strategies later. EPA is allowing areas to grandfather projects included in the first three years of the currently conforming plan and TIP in order to provide stability for planning.

Most commenters supported the primary option EPA is finalizing today, and gave a variety of reasons. Several stakeholders commented that this option allows some continuity for transportation planning, since ideally it allows the TIP to continue in the short term while changes to the SIP are underway. Another commenter noted that since this option minimizes the disruption of projects in the first three years of the TIP, it limits the financial and legal risk to local governments when they undertake local bond programs to finance these projects. Another commenter noted that SIPs may be disapproved for numerous reasons outside of the control of the DOT or MPO, and stopping all transportation projects immediately is not in the public's best interest. Finally, a commenter added that since the projects that would be allowed to proceed would have been included in a plan and TIP found to conform previously, it seems reasonable to allow these projects to advance.

Some commenters supported aligning the timing of conformity consequences of SIP disapproval with imposition of highway sanctions, which was option 4 in the proposal. Commenters suggested that this option would simplify communication, make the rule more consistent, and eliminate a perceived inequity with stationary sources. However, for the reasons stated above, EPA believes that there is no appropriate basis to find new projects that were not included in the previously conforming plan/TIP to conform when the SIP has been disapproved without a protective finding. Commenters supporting option 4 did not identify a means by which to claim that such projects would not contribute to violations of the standards.

C. Discussion of Specific Comments

Some objections to the legality of the primary option were raised. One commenter objected to any project approvals based on plans and TIPs that have lapsed, since even projects in the first three years cannot satisfy the statutory test for coming from a conforming plan and TIP if the conformity of the plan and TIP has lapsed. EPA agrees that projects cannot be approved if the plan and TIP have

lapsed. However, in this situation, the conformity status of existing plans and TIPs is not lapsing. The plan and TIP is frozen such that no new projects can be added, but projects in the first three years can proceed to project-level approval. EPA is grandfathering plans and TIPs that have already been found to conform. EPA agrees that new plans and TIPs or plan/TIP amendments cannot be found to conform after the 120-day grace period.

Another objection raised was that EPA cannot allow plans, TIPs, or projects to conform based on SIPs that have been disapproved, since conformity must be based on the applicable implementation plan. EPA agrees with this statement as well. Today's action makes it clear that an area cannot find any new projects to conform once the SIP has been disapproved without a protective finding. EPA is only allowing areas to approve projects that are within the first three years of a plan and TIP that has already been found to conform, for the two years prior to lapsing.

A commenter objected to codification of EPA's committal SIP policy by the adoption of the definition of "protective finding" and the authorization for protective findings in § 93.120.

EPA responds by clarifying that granting a protective finding does not codify a committal SIP policy. By giving a SIP a protective finding, EPA does not mean to imply that these SIPs are in any way approvable. Rather, by disapproving the SIP, EPA is stating that the SIP does not meet Clean Air Act SIP requirements. Granting a protective finding merely allows an area to use the motor vehicle emissions budget in the disapproved SIP to demonstrate conformity, where appropriate. As other commenters stated, there are many reasons why a SIP could be disapproved by EPA, some of which would have nothing to do with the integrity of the motor vehicle emissions budget. A protective finding ensures that the transportation community is not penalized as a result of a SIP failure when the emissions budget in the SIP is adequate to serve as the basis of a conformity determination.

Finally, a commenter believed that prohibiting any project funding except for grandfathered projects after the imposition of highway sanctions (i.e., a conformity lapse) is not consistent with the policy adopted by Congress for the imposition of sanctions. The commenter stated that the conformity rule should be revised to explicitly adopt the policy of prohibiting funding only for highway capacity expansion while providing funding for all those projects that will

improve air quality identified in Clean Air Act section 179(b)(1)(B). Section 179(b)(1)(B) lists the types of projects that can proceed under sanctions.

However, sanctions and conformity are two different parts of the Clean Air Act, and serve quite different purposes. Because certain activities can proceed under sanctions does not mean that these types of projects should not have to undergo a conformity analysis prior to implementation, or should be permanently grandfathered from conformity requirements. Furthermore, EPA does allow transportation control measures in approved SIPs to proceed even during a conformity lapse. This is consistent with the sanctions policy's provision for projects that benefit air quality to proceed.

XII. Traffic Signal Synchronization

On September 24, 1996, Congress amended the Clean Air Act to state that traffic signal synchronization projects are exempt from conformity determinations prior to their funding, approval, or implementation. However, once these projects are funded, approved, or implemented (whichever occurs first), they are to be included in the conformity determinations for future transportation plans, TIPs, and projects.

The final rule reflects this Clean Air Act amendment in new § 93.128, "Traffic signal synchronization projects." This section states that traffic signal synchronization projects may be approved, funded, and implemented without a conformity determination. However, all subsequent regional emissions analyses required by §§ 93.118 and 93.119 for transportation plans, TIPs, or projects not from a conforming plan and TIP must include such regionally significant traffic signal synchronization projects.

In the preamble to the proposal, prior to congressional action on this issue, EPA had discussed whether traffic signal synchronization projects should be exempt from conformity. This topic was included because several stakeholders had advocated the exemption of signal synchronization projects on the basis of positive air quality and congestion mitigation impacts. EPA did not propose to exempt these projects for reasons explained in the proposal's preamble. EPA received a few comments on both sides of this issue. However, EPA is now promulgating this change to the conformity rule without repropounding because Congress has already amended the Clean Air Act and any additional comments could not change the outcome. The Clean Air Act has exempted these projects from advance

conformity determinations as a matter of law, and EPA is now merely reflecting this statutory change in the regulations. EPA finds good cause to dispense with notice and comment because EPA has no discretion in this matter and is merely clarifying the rule to be consistent with the amended statute.

XIII. Conformity SIPs

As specified in the original November 1993 conformity rule and § 51.390(b) of today's final rule, the federal conformity requirements no longer govern conformity determinations once EPA approves a state conformity SIP revision. The provisions of the approved SIP apply instead. Therefore, the new flexibilities found in today's rulemaking will not take effect in areas that already have an approved conformity SIP until the state prepares a new conformity SIP and it is approved by EPA.

Several stakeholders commented that this process could take too long to give areas adequate relief. Commenters suggested several possible solutions. For example, EPA could grant relief from the build/no-build test without the approval of the new conformity SIP, or today's rule could become effective upon submission of a formal statement that the state is preparing a new conformity SIP. These suggestions cannot be implemented because once EPA approves a state's conformity SIP, that SIP becomes federally enforceable law, and cannot be changed without notice-and-comment rulemaking. The conformity rule itself cannot change the applicability of approved conformity SIPs.

Another commenter suggested that EPA add language to the rule to automatically approve conformity SIPs that adopt the EPA language by reference. However, SIP approval requires public notice and comment in the **Federal Register** in accordance with the APA; it cannot be given automatically. Furthermore, there are sections of the conformity SIP, for example, the consultation section, that cannot be adopted by reference or verbatim because they must be tailored for the state's own circumstances.

However, EPA understands areas' desire to determine conformity using the procedures in today's final rule, and EPA will give priority to processing conformity SIP revisions designed to incorporate these changes in those areas with approved conformity SIPs. EPA also commits to expedite the approval of conformity SIP revisions that, to the extent possible, incorporate the amendments verbatim or by reference.

EPA is requiring conformity SIPs to be submitted to EPA within 12 months of

today's rulemaking. One commenter stated that the 12-month timeframe for revising conformity SIPs is too short given that state air quality agencies would have to hire new staff to accomplish the task, and that 12 months is inconsistent with the Clean Air Act provisions that allow 18 months after a SIP call for an area to remedy its deficiencies. EPA agrees that experience has shown 12 months to be a very ambitious deadline. However, Clean Air Act section 176(c)(4)(C) is very specific in its intent that states submit conformity SIPs within 12 months of EPA's rules. EPA does not believe that the Clean Air Act's general language regarding SIP calls should be used to override the specific timeframe for submitting conformity SIPs that is evidenced in Clean Air Act section 176(c)(4)(C). In the case of a SIP call, EPA is allowed to establish reasonable deadlines not to exceed 18 months for an area to correct its SIP inadequacies. However, because it cannot be argued that revising a conformity SIP to include these amendments is more time-consuming than preparing an original conformity SIP, there is no appropriate basis to claim that the general SIP call language should override the specific intent of Congress regarding deadlines for submission of conformity SIPs relative to promulgation of federal conformity rules.

XIV. Hot-Spot Tests

Most commenters supported the clarification to § 93.123, "Procedures for determining localized CO and PM-10 concentrations (hot-spot analysis)," which allows the use of procedures other than "Guideline" models in hot-spot analyses if the alternate procedures are developed through the interagency consultation process and are approved by the EPA Regional Administrator.

A few commenters believed that the CO hot-spot requirements for all projects affecting intersections of level of service (LOS) D, E, and F are too stringent and burdensome when compared to the realized benefits from such analyses. Other commenters thought that the requirements were too prescriptive, because LOS D does not automatically indicate an air quality problem. One commenter suggested that the conformity rule should only require hot-spot analyses for the worst, most representative intersection on each major street impacted by a project, rather than all intersections that fit the current rule's hot-spot criteria. EPA believes no change to the proposal is necessary to address these concerns because it does have flexibility that allows areas to develop their own

protocols that have different screening mechanisms.

A few commenters suggested that the conformity rule should be clarified to allow projects which decrease the likelihood of public exposure to exceedances of the NAAQS. For example, commenters stated that a project should be allowed to make a violation worse in a place not frequented by the public if it improves air quality and eliminates violations where public exposure is more likely. However, Clean Air Act section 176(c)(1)(B) states that transportation projects must not cause or contribute to any new violation of any standard in any area, or increase the frequency or severity of any existing violation of any standard in any area. It is not public exposure to a violation of a standard that the Clean Air Act language prohibits; it prohibits any violation of any standard in any area. The conformity rule cannot override the Clean Air Act to make exceptions that create new or worsen existing violations.

XV. TCM Flexibility

As discussed in the proposal preamble, EPA remains committed to issuing guidance on how areas can substitute TCMs in previously approved SIPs without additional EPA approvals. EPA also stated in the proposal that development of such a substitution mechanism is possible under existing EPA SIP policy, so this final rule does not address the issue.

XVI. Conformity and the Proposed NAAQS Revisions

Several commenters requested information on how the revisions of the ozone and particulate matter (PM) NAAQS standards would affect conformity. EPA issued a notice of proposed policy entitled, "Interim Implementation Policy on New or Revised Ozone and Particulate Matter NAAQS" (61 FR 65752, December 13, 1996), which proposes how current programs would be affected while states are developing plans to implement the new NAAQS. This proposed policy notice specifically discusses conformity. A final policy for implementing the one hour ozone and pre-existing PM NAAQS will be published in the **Federal Register** in September 1997.

EPA proposed in its December 1996 notice that conformity determinations would not be required to address the new NAAQS until SIPs addressing the new NAAQS are approved by EPA. New nonattainment areas would not be subject to conformity until EPA approves the SIPs that address these

standards. Existing nonattainment and maintenance areas would not have to consider the 8-hour ozone standard or the PM-2.5 standard in their conformity determinations until EPA approved SIPs addressing those pollutants.

In general, the existing control strategy SIPs and maintenance plans that establish motor vehicle emissions budgets will remain in force until they are superseded by new or revised SIPs that have been approved by EPA. Thus, conformity will continue as usual in existing nonattainment and maintenance areas for several years. Areas that have not submitted post-1996 rate-of-progress plans or attainment demonstrations for the one hour ozone standard would be required to conform to the 15% SIP until a post-1996 plan or new attainment demonstration is submitted.

In such areas, conformity to that plan would not be required, and these areas would continue to demonstrate conformity to the 15% SIP. Areas that are not required to submit control strategy SIPs (e.g., marginal areas) and have not been demonstrating conformity to motor vehicle emissions budgets would be required to continue demonstrating conformity using the emission reduction tests until SIPs with motor vehicle emissions budgets are submitted. Areas with approved maintenance plans would continue demonstrating conformity using the budgets established by those plans.

States are free to establish, through the SIP process, a motor vehicle emissions budget that addresses the new NAAQS in advance of a complete SIP attainment demonstration. That is, a state could submit a motor vehicle emissions budget that does not demonstrate attainment but is consistent with projections and commitments to control measures and achieves some progress toward attainment. Such a budget would apply for conformity purposes in addition to existing budgets addressing the old NAAQS (i.e., a SIP that does not demonstrate attainment of the new NAAQS would not supersede existing control strategy SIPs).

Today's final conformity rule does not include any changes specifically intended to address the NAAQS revisions. No changes are necessary in the short term because the existing conformity process will continue for several years. The Federal Advisory Committee Act (FACA) Subcommittee for Ozone, PM and Regional Haze Implementation Programs is discussing the longer-term conformity issues, and EPA's decisions will be published in future policy notices. In addition, EPA will be promulgating a conformity rule

addressing transitional ozone areas under the new standard by December 1998.

XVII. Minor Changes to the Rule

A. Definitions

This final rule includes three new definitions in § 93.101. For the purposes of this final rule, EPA has defined "written commitment" to mean a commitment that includes a description of the action to be taken; a schedule for the completion of the action; a demonstration that funding necessary to implement the action has been authorized by the appropriating or authorizing body; and an acknowledgment that the commitment is an enforceable obligation under the SIP. The conformity rule uses the term "written commitment" with respect to SIP commitments to control measures, and also with respect to commitments to project-level emissions mitigation or control measures as part of a conformity determination. As described in § 93.125(c), these latter commitments are enforceable under the conformity SIP. As is the case with any other type of SIP commitments, written commitments as defined by the conformity rule must be made by an agency that has legal authority to implement the action in question.

EPA is defining the term "written commitment" because a commenter requested it, and EPA agrees that this will ease implementation by clarifying EPA's intent. This definition is consistent with EPA's historical implementation of the conformity rule.

EPA is also defining the term "safety margin" to mean the amount by which the total projected emissions from all sources of a given pollutant are less than the total emissions that would satisfy the applicable Clean Air Act requirement for reasonable further progress, attainment, or maintenance. EPA has added a reference to that term in § 93.118(e)(4), which lists the requirements for the adequacy of submitted SIPs. This section specifies that documentation of any changes to established safety margins is a criterion for the adequacy of a submitted SIP. The term "safety margin" is also used in § 93.124(b), although it is used and defined in that section in a specific context. This definition is consistent with the historical implementation of the conformity rule and with the definition in § 93.124(b).

EPA is defining "lapse" to mean that the conformity determination for a transportation plan or TIP has expired, and thus there is no currently conforming transportation plan and TIP.

B. Consultation

EPA is making two minor changes to the consultation section in response to comments on the proposal. One commenter suggested that the public consultation requirements of § 93.105(e) should be included in the conformity SIP. EPA agrees with this commenter and has modified § 93.105(a) to clarify that the public consultation requirements described in § 93.105(e) must also be required by the conformity SIP. Because the federal conformity rule ceases to apply once the conformity SIP has been approved, the requirements of § 93.105(e) must be required by the conformity SIP or the SIP would not provide for appropriate public input.

Section 93.105(e) requires public consultation consistent with the requirements of 23 CFR 450.316(b) and articulates a few specific requirements. EPA intends for the conformity SIP to reiterate these statements; EPA does not intend for the conformity SIP to actually include the specific public consultation procedures that an area develops under 23 CFR 450.316(b).

EPA is also adding a new element to the list of processes for which consultation procedures must be developed. Section 93.105(c)(1)(vii) requires areas to establish a process for choosing conformity tests and methodologies for isolated rural nonattainment and maintenance areas, as required by § 93.109(g)(2)(iii). (Refer to section V. of this preamble, "Rural Nonattainment and Maintenance Areas" for a discussion of the choices of conformity tests that are available to rural areas.) Of course, states without isolated rural nonattainment and maintenance areas would not need to develop such procedures.

As explained in the proposal preamble, EPA had not proposed to amend § 51.402/§ 93.105 of the original conformity rule to add this element to the list of processes for which consultation procedures must be developed, because EPA believed it was clear that consultation would be necessary to use the new rural provision. Commenters had mixed opinions about whether and how the new consultation needs should be integrated into the conformity rule. Some commenters did not believe that the conformity rule needed to be changed. However, some thought that further guidance regarding necessary changes in areas' consultation procedures would be useful. Given these comments, EPA decided to add the new consultation requirement to the conformity rule for clarity and so that the rule could serve as a comprehensive

list of items that consultation procedures must address.

One commenter requested that EPA explain that Memoranda of Understanding, or MOUs, can be used to establish interagency consultation procedures. The commenter is correct that MOUs can be used to establish interagency consultation procedures, provided that the MOU is enforceable under state law. In order for the MOU to be enforceable, all agencies that are covered by the conformity rule must sign the MOU, including federal agencies and the recipients of funds designated under title 23 U.S.C. or the Federal Transit Laws (i.e., non-federal project sponsors). In addition, the conformity SIP must include a rule that requires all future parties covered by the rule, including new recipients of funds designated under title 23 U.S.C. or the Federal Transit Laws, to sign the MOU. This ensures that the MOU approach will continue to apply to all subject parties. EPA does not believe that any regulatory changes are needed to address this issue.

C. Changes to § 93.109

Section 93.109, "Criteria and procedures for determining conformity of transportation plans, programs, and projects: General," describes which conformity tests apply and when they apply for each pollutant and for rural areas. This section has been revised to reflect changes discussed elsewhere in this preamble. In addition, this section has been slightly revised so that its description of conformity requirements does not refer solely to an area's nonattainment classification. The section now also refers to the control strategy SIP requirements for a given classification. EPA believes this clarifies the conformity rule and makes it more flexible in the case of future revisions to the classification system, which could occur if the NAAQS are revised. These clarifications do not change the substance of the section's requirements.

XVIII. 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. Paperwork Reduction Act

This final rule does not impose any new information collection requirements and results in no change to the currently approved collection requirements. OMB has approved the information collection requirements contained in this rule under the provisions of the Paperwork Reduction Act, 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, and assigned OMB Control Number 2132-0529.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency 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. The OMB control numbers for DOT's regulations are listed in 5 CFR Part 1320.

Send any comments on the recordkeeping and reporting requirements of Transportation Conformity to: Mr. Sean Libberton, U.S. 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 Analysis

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 rule will not have a significant economic impact on a substantial number of small entities.

D. Submission to Congress and the Comptroller General

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in today's **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

E. 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. These rule amendments relax requirements of the previously applicable conformity rule, and thus do not impose any additional burdens. 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, Air pollution control, Carbon monoxide, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Transportation, Volatile organic compounds.

40 CFR Part 93

Administrative practice and procedure, Air pollution control, Carbon monoxide, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Transportation, Volatile organic compounds.

Dated: July 31, 1997.

Carol M. Browner,
Administrator.

For the reasons set out in the preamble, 40 CFR parts 51 and 93 are amended as follows:

PART 51—[AMENDED]

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

Authority: 42 U.S.C. 7401–7671q.

2. Subpart T is revised 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 subpart and part 93, subpart A, of this chapter 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 this subpart and part 93, subpart A, of this chapter. 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 this subpart and part 93, subpart A, of this chapter only if the State's conformity provisions apply equally to non-federal as well as Federal entities.

(b) The Federal conformity rules under part 93, subpart A, 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 conformity implementation plan revision required by this subpart. 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, subpart A, 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 submits a revision to 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 subpart, the plan must address all requirements of part 93, subpart A, of this chapter in a manner which gives them full legal effect. In particular, the revision shall incorporate the provisions of the following sections of part 93, subpart A,

of this chapter 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 the following 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.

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

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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

§ 93.100 Purpose.

The purpose of this subpart is to implement section 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 (42 U.S.C. 7401 et seq.).

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.

Forecast period with respect to a transportation plan is the period covered by the transportation plan pursuant to 23 CFR part 450.

FTA means the Federal Transit Administration of DOT.

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.

Hot-spot analysis is an estimation of likely future localized CO and PM₁₀ 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.

Lapse means that the conformity determination for a transportation plan or TIP has expired, and thus there is no currently conforming transportation plan and TIP.

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. 5303. 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 section 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 a submitted control strategy implementation plan revision contains adopted control measures or written commitments to adopt enforceable control measures that fully satisfy the emissions reductions requirements relevant to the statutory provision for which the implementation plan revision was submitted, such as reasonable further progress or attainment.

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.

Safety margin means the amount by which the total projected emissions from all sources of a given pollutant are less than the total emissions that would satisfy the applicable requirement for reasonable further progress, attainment, or maintenance.

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 first sentence of this definition, 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.

Written commitment for the purposes of this subpart means a written commitment that includes a description of the action to be taken; a schedule for the completion of the action; a demonstration that funding necessary to implement the action has been authorized by the appropriating or authorizing body; and an acknowledgment that the commitment is an enforceable obligation under the applicable implementation plan.

§ 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 subpart 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

(NO₂), and particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers (PM₁₀).

(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 NO₂ areas; and

(iii) VOC, NO_x, and PM₁₀ in PM₁₀ 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 PM₁₀ 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 subpart 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, PM₁₀ or NO₂ 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), resolution of conflicts, and public consultation as described in paragraphs (a) through (e) of this section. Public consultation procedures will be developed in accordance with the requirements for public involvement in 23 CFR part 450.

(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 following general factors 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(b), projects located at sites in PM₁₀ 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 PM₁₀ hot-spot analysis;

(vi) Notification of transportation plan or TIP revisions or amendments which merely add or delete exempt projects listed in § 93.126 or § 93.127; and

(vii) Choosing conformity tests and methodologies for isolated rural nonattainment and maintenance areas, as required by § 93.109(g)(2)(iii).

(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; and

(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 and have an urbanized population greater than 200,000 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 through 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 through 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) Table 1 in this paragraph indicates the criteria and procedures in §§ 93.110 through 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 follows:

TABLE 1.—CONFORMITY CRITERIA

All Actions at all times: § 93.110 § 93.111 § 93.112	Latest planning assumptions. Latest emissions model. Consultation.
Transportation Plan: § 93.113(b) § 93.118 or § 93.119	TCMs. Emissions budget or Emission reduction.
TIP: § 93.113(c) § 93.118 or § 93.119	TCMs. 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 § 93.117	CO and PM ₁₀ hot spots. PM ₁₀ control measures.
Project (Not From a Conforming Plan and TIP): § 93.113(d) § 93.114	TCMs. Currently conforming plan and TIP.
§ 93.116 § 93.117 § 93.118 or § 93.119	CO and PM ₁₀ hot spots. PM ₁₀ control measures. Emissions budget or Emission reduction.

(c) *Ozone nonattainment and maintenance areas.* In addition to the criteria listed in Table 1 in paragraph (b) of this section 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:

(1) In ozone nonattainment and maintenance 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 ozone nonattainment areas that are required to submit a control strategy implementation plan revision (usually moderate and above 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 implementation plan 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% plan 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) Ozone nonattainment areas that have not submitted a maintenance plan and that are not required to submit a control strategy implementation plan revision (usually marginal and below areas) 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).

(5) 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 budget test as required by § 93.118, using the motor vehicle emissions of ozone precursors in the most recent year of clean data as motor vehicle emissions budgets, if such budgets are established by the EPA rulemaking that determines that the area has clean data.

(d) *CO nonattainment and maintenance areas.* In addition to the criteria listed in Table 1 in paragraph (b) of this section 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:

(1) FHWA/FTA projects in CO nonattainment or maintenance areas must satisfy the hot spot test required by § 93.116(a) 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 nonattainment and maintenance 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) Except as provided in paragraph (d)(4) of this section, in 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 implementation plan or a previously submitted control strategy implementation plan revision or maintenance plan.

(4) CO nonattainment areas that have not submitted a maintenance plan and that are not required to submit an attainment demonstration (e.g., moderate CO areas with a design value of 12.7 ppm or less or not classified CO areas) 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 (d)(2) of this section).

(e) *PM₁₀ nonattainment and maintenance areas.* In addition to the criteria listed in Table 1 in paragraph (b) of this section that are required to be satisfied at all times, in *PM₁₀* 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:

(1) FHWA/FTA projects in *PM₁₀* nonattainment or maintenance areas must satisfy the hot spot test required by § 93.116(a).

(2) In *PM₁₀* nonattainment and maintenance 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 *PM₁₀* 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 implementation plan or a previously submitted control strategy implementation plan revision or maintenance plan; or

(iii) If the submitted implementation plan revision is a demonstration of impracticability under CAA section 189(a)(1)(B)(ii) and does not demonstrate attainment.

(f) *NO₂ nonattainment and maintenance areas.* In addition to the criteria listed in Table 1 in paragraph (b) of this section that are required to be satisfied at all times, in *NO₂* 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:

(1) In *NO₂* nonattainment and maintenance 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 *NO₂* 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

implementation plan 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 *PM₁₀* 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) through (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 (including regional emissions analysis for *NO_x* in all ozone nonattainment and maintenance areas, notwithstanding § 93.119(d)(2)); or

(C) As demonstrated by the air quality dispersion model or other air quality modeling technique used in the attainment demonstration or maintenance plan, the FHWA/FTA project, in combination with all other

regionally significant projects expected in the area in the timeframe of the statewide transportation plan, must 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(c)(1)(vii) 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 department of transportation 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 through 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 subpart 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 (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 of § 93.109(b) 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 PM₁₀ 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 PM₁₀ violations or increase the frequency or severity of any existing CO or PM₁₀ violations in CO and PM₁₀ 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 PM₁₀ control measures.

The FHWA/FTA project must comply with PM₁₀ 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 PM₁₀ 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) through (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 implementation plan 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) 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 period of 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) EPA will not find a motor vehicle emissions budget in a submitted control strategy implementation plan revision or maintenance plan to be adequate for transportation conformity purposes unless the following minimum criteria are satisfied:

(i) The submitted control strategy implementation plan revision or maintenance plan was endorsed by the Governor (or his or her designee) and was subject to a State public hearing;

(ii) Before the control strategy implementation plan or maintenance plan was submitted to EPA, consultation among federal, State, and local agencies occurred; full implementation plan documentation was provided to EPA; and EPA's stated concerns, if any, were addressed;

(iii) The motor vehicle emissions budget(s) is clearly identified and precisely quantified;

(iv) The motor vehicle emissions budget(s), when considered together with all other emissions sources, is consistent with applicable requirements for reasonable further progress, attainment, or maintenance (whichever is relevant to the given implementation plan submission);

(v) The motor vehicle emissions budget(s) is consistent with and clearly related to the emissions inventory and the control measures in the submitted control strategy implementation plan revision or maintenance plan; and

(vi) Revisions to previously submitted control strategy implementation plans or maintenance plans explain and document any changes to previously submitted budgets and control measures; impacts on point and area source emissions; any changes to established safety margins (see § 93.101 for definition); and reasons for the changes (including the basis for any changes related to emission factors or estimates of vehicle miles traveled).

(5) Before determining the adequacy of a submitted motor vehicle emissions budget, EPA will review the State's compilation of public comments and response to comments that are required to be submitted with any implementation plan. EPA will document its consideration of such

comments and responses in a letter to the State indicating the adequacy of the submitted motor vehicle emissions budget.

(6) 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 determinations 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) through (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 CAA 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 § 93.122 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:

(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 PM₁₀ and NO₂ nonattainment areas; marginal and below ozone nonattainment areas and other ozone nonattainment areas that are not subject to the reasonable further progress requirements of CAA 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 PM₁₀ 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 areas;

(2) NO_x in ozone areas, unless the EPA Administrator determines that additional reductions of NO_x would not contribute to attainment;

(3) CO in CO areas;

(4) PM₁₀ in PM₁₀ areas;

(5) Transportation-related precursors of PM₁₀ in PM₁₀ nonattainment and maintenance 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 area are a significant contributor to the PM₁₀ nonattainment problem and has so notified the MPO and DOT; and

(6) NO_x in NO₂ 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) 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 required by paragraphs (b) and (c) of this section 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) 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 CAA. No new transportation plan, TIP, or project may be found to conform until another control strategy implementation plan revision fulfilling the same CAA 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 CAA 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(s) in the disapproved control strategy implementation plan, unless another control strategy implementation plan revision has been submitted and its motor vehicle emissions budget(s) applies for transportation conformity purposes, pursuant to § 93.109.

(3) In disapproving a control strategy implementation plan revision, EPA would give a protective finding where a submitted plan contains adopted control measures or written commitments to adopt enforceable control measures that fully satisfy the emissions reductions requirements relevant to the statutory provision for which the implementation plan revision was submitted, such as reasonable further progress or attainment.

(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 CAA 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 CAA, 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 are met:

(1) The project was included in the first three years of the most recently conforming transportation plan and TIP (or the conformity determination's regional emissions analyses), 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 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 vehicle 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 written 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 or maintenance area VMT 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) through (3) 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-based travel models 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. Agencies must discuss these modeling procedures and practices through the interagency consultation process, as required by § 93.105(c)(1)(i). Network-based travel models must at a minimum satisfy the following requirements:

(i) Network-based travel models must be validated against observed counts (peak and off-peak, if possible) for a base year that is not more than 10 years prior to the date of the conformity determination. Model forecasts must be analyzed for reasonableness and

compared to historical trends and other factors, and the results must be documented;

(ii) Land use, population, employment, and other network-based travel model assumptions must be documented and based on the best available information;

(iii) Scenarios of land development and use must be consistent with the future transportation system alternatives for which emissions are being estimated. The distribution of employment and residences for different transportation options must be reasonable;

(iv) A capacity-sensitive assignment methodology must be used, and emissions estimates must be based on a methodology which differentiates between peak and off-peak link volumes and speeds and uses speeds based on final assigned volumes;

(v) Zone-to-zone travel impedances used to distribute trips between origin and destination pairs must be in reasonable agreement with the travel times that are estimated from final assigned traffic volumes. Where use of transit currently is anticipated to be a significant factor in satisfying transportation demand, these times should also be used for modeling mode splits; and

(vi) Network-based travel models must be reasonably sensitive to changes in the time(s), cost(s), and other factors affecting travel choices.

(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-based travel model.

(3) Highway Performance Monitoring System (HPMS) estimates of vehicle miles traveled (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-based travel models, a factor (or factors) may be developed to reconcile and calibrate the network-based travel 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 between HPMS and network-based travel models, such as 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).

(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 VMT per person. These methods must also consider future economic activity, transit alternatives, and transportation system policies.

(d) *PM₁₀ from construction-related fugitive dust.* (1) For areas in which the implementation plan does not identify construction-related fugitive PM₁₀ as a contributor to the nonattainment problem, the fugitive PM₁₀ emissions associated with highway and transit project construction are not required to be considered in the regional emissions analysis.

(2) In PM₁₀ nonattainment and maintenance areas with implementation plans which identify construction-related fugitive PM₁₀ as a contributor to the nonattainment problem, the regional PM₁₀ emissions analysis shall consider construction-related fugitive PM₁₀ and shall account for the level of construction activity, the fugitive PM₁₀ 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 PM₁₀ concentrations (hot-spot analysis).

(a) *CO hot-spot analysis.* (1) The demonstrations required by § 93.116 ("Localized CO and PM₁₀ 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). These procedures shall be used in the following cases, unless different procedures developed through the interagency consultation process required in § 93.105 and approved by the EPA Regional Administrator are used:

(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) *PM₁₀ 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.

(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 this paragraph (b) 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) PM₁₀ 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 PM₁₀ 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 an implementation plan revision which assigns some or all of this safety margin to highway and transit mobile sources for the purposes of conformity. Such an implementation plan 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, unless the implementation plan establishes appropriate 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 implementation plan 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 PM₁₀ 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 of this section 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 of this section 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 follows:

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.

Note: ¹In PM₁₀ 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 of this section are exempt from regional emissions analysis requirements. The local effects of these

projects with respect to CO or PM₁₀ 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 of this section 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 that it has potential regional impacts for
(in the case of a transit project) concur any reason. Table 3 follows:

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.

§ 93.128 Traffic signal synchronization projects.

Traffic signal synchronization projects may be approved, funded, and implemented without satisfying the requirements of this subpart. However,

all subsequent regional emissions analyses required by §§ 93.118 and 93.119 for transportation plans, TIPs, or projects not from a conforming plan and TIP must include such regionally

significant traffic signal synchronization projects.

[FR Doc. 97–20968 Filed 8–14–97; 8:45 am]

BILLING CODE 6560–50–P

Final Rule

Friday
August 15, 1997

Part III

**Environmental
Protection Agency**

**40 CFR Part 799
Toxic Substances Control Act Test
Guidelines; Final Rule**

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 799**

[OPPTS-42193; FRL-5719-5]

RIN 2070-AB76

Toxic Substances Control Act Test Guidelines**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: This rule establishes 11 Toxic Substances Control Act (TSCA) health effects test guidelines in the Code of Federal Regulations (CFR). Establishment of these guidelines is necessary to ensure enforceable test standards in test rules promulgated under section 4 of TSCA. Codification of this series of TSCA test guidelines does not by itself impose obligations upon any person. Obligations are only imposed when these guidelines are cross-referenced in a test rule promulgated under section 4 of TSCA.

DATES: This rule is effective on August 15, 1997.

FOR FURTHER INFORMATION CONTACT:

Susan Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-543B, 401 M St., SW., Washington, DC 20460; telephone: (202) 554-1404; TDD: (202) 554-0551; e-mail: TSCA-Hotline@epamail.epa.gov. For specific information regarding this action or related activities, please contact Roger Nelson, Chemical Control Division, OPPT; telephone: (202) 260-8163; e-mail: nelson.roger@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: This final rule establishes a new series of TSCA test guidelines in the CFR.

I. Introduction

Section 4(b)(1)(B) of TSCA requires that test rules promulgated under the authority of TSCA section 4 include "standards for the development of test data for such substance or mixture * * *." Test rules promulgated under TSCA section 4 must specify the standards for the development of data. Standards established in test rules for the development of data must specify how the study is to be conducted, what data will be collected, and how the data will be analyzed. The Agency has found that these specifications to a large degree can be standardized into a common set of protocols, or, as the Agency terms them, "guidelines." These guidelines are organized by testing endpoint. Each test

standard can modify these guidelines as needed for an individual test substance.

The Agency uses a system where standardized guidelines are organized by testing endpoint and codified in a subpart of this part. When a test rule is promulgated, the test standard specified in the test rule cross-references the guideline for the bulk of the testing requirements. In this context, the public is given notice of, and an opportunity to comment on, the guidelines as they are applied in chemical-specific test rules. This approach eliminates the need to repeat the same test specifications for each substance-specific test rule since most of the specifications for testing do not change across substances. The test specifications in a guideline can be varied, when necessary, to the specific requirements of a test rule by language in the test rule itself.

In 1985, the Agency established a set of TSCA test guidelines in 40 CFR parts 795 through 798 (50 FR 39252, September 27, 1985). These guidelines were established as standardized protocols for laboratory testing of an effect or characteristic deemed important for the evaluation of health or environmental hazards of a chemical. Standardized guidelines are necessary for the establishment of enforceable test standards in test rules promulgated under section 4 of TSCA.

The Agency has over time amended and improved these guidelines (52 FR 19072, May 20, 1987). In order to reduce the text of the CFR, the Agency deleted those guidelines which had not been cited in any test rules (60 FR 31917, June 19, 1995 (FRL-4955-2)).

II. OPPTS Harmonized Test Guidelines

EPA is undertaking a comprehensive modification, or harmonization, of its pesticides and toxics guidelines for testing of health effects, environmental effects, and chemical fate. The rationale for this harmonization is to incorporate state of the art science, and to minimize variations among the protocols contained in:

1. Test guidelines developed by the EPA Office of Pesticide Programs (OPP), which appeared in publications of the National Technical Information Service.
2. The series of TSCA test guidelines established in 1985, which are contained in 40 CFR parts 795, 796, 797, and 798.
3. Guidelines published by the Organization for Economic Cooperation and Development (OECD).

Harmonization operates as follows: EPA scientists develop guidelines (or modify existing guidelines) for specific endpoints. The new or rewritten guidelines are reviewed by other

Agency experts and, in some instances, presented at domestic and international colloquia to solicit the views of recognized experts and the regulated community. The draft harmonized guidelines are made available as public drafts. A notice is published in the **Federal Register** announcing their availability and soliciting public comment.

Seven of the 11 health effects test guidelines that are being codified in subpart H of 40 CFR part 799 have their origin in this harmonization process. A notice was published in the **Federal Register** of June 20, 1996, (61 FR 31522 (FRL-5367-7)) announcing the availability of the proposed test guidelines for Series 870—Health Effects Test Guidelines and soliciting public comment. Comments were received, and a meeting of the Agency's Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) was held on October 29 and 30, 1996. The SAP, an advisory committee consisting of scientific experts both inside and outside the U.S. Government, reviewed the guidelines and made comments. The Agency reviewed these comments in developing the harmonized health effects guidelines.

Four of the 11 guidelines (§§ 799.9510, 799.9530, 799.9538, and 799.9539) were initially developed by the OECD.

III. TSCA Test Guidelines

Harmonization has resulted in significantly improved guidelines. However, creating a single set of guidelines which can be used by both OPP, in its administration of the FIFRA and the Federal Food, Drug and Cosmetic Act (FFDCA), and the Office of Pollution Prevention and Toxics (OPPT), which administers TSCA presented certain challenges.

Under FIFRA, test guidelines are used in an interactive process between the Agency and registrants seeking registration of pesticides or food residue tolerances. Flexibility to tailor required testing to individual circumstances is critical, and the Agency has considerable discretion to determine whether submitted test results are adequate to support the requested action. Under this scheme, registrants have an intrinsic motivation to conduct well-grounded testing. Thus, pesticide testing protocols tend to have few absolute requirements specifying the details of the conduct of the testing.

By contrast the Agency is required under section 4 of TSCA to impose prescriptive test requirements by notice and comment rulemaking. Rules

promulgated under section 4 of TSCA specify classes of affected parties, usually manufacturers and processors of the chemical being specified for testing, rather than interacting with companies on an individual basis. These rulemakings typically take years to complete. Without initiating another rulemaking process, the Agency has the ability to require further testing only if the tests were not conducted in accordance with the procedures specified in the test rule. In addition, the Agency has an alternative process of negotiating TSCA testing requirements via enforceable consent agreements (ECAs), but these agreements require the consent of all the parties involved.

Under TSCA section 4 enforceable test standards, much in the conduct of these test protocols is left to the judgment of those professionals conducting the testing. EPA believes that certain provisions must be mandatory whenever the guidelines are cross-referenced in specific test rules.

Therefore, the Agency has used the OPPTS harmonized health effects test guidelines developed using the public notice and comment process described in Unit II. of this preamble as well as certain OECD guidelines to create the TSCA-specific test guidelines which are the subject of this rule. Future TSCA section 4 test rules will cross-reference part 799 guidelines rather than the

older, 1985 non-harmonized guidelines in 40 CFR parts 795 through 798. The only significant difference between the TSCA test guidelines and the OPPTS harmonized test guidelines is that certain recommended procedures in the OPPTS harmonized test guidelines are made mandatory (i.e., the guideline states that they "shall" be carried out).

IV. Codification in 40 CFR Part 799

The Agency had originally planned not to publish the guidelines in the CFR, but to instead make the guidelines available via other means (such as the Internet) and reference the guidelines in specific test rules using the incorporation by reference procedures provided by 5 U.S.C. 552(a)(1)(E) and 1 CFR part 51. In the **Federal Register** document proposing the TSCA section 4 test rule for 21 hazardous air pollutant substances (HAPs) (61 FR 33178, 33187, June 26, 1996 (FRL-4869-1)), the Agency stated that it was considering using incorporation by reference. Subsequently, however, the Director of the Office of Federal Register advised EPA that the planned TSCA section 4 process for guideline incorporation was not eligible for incorporation by reference under 1 CFR part 51. Therefore, the Agency finds it necessary to codify a separate set of TSCA test guidelines into the CFR. As discussed in this preamble, the TSCA guidelines are

essentially those resulting from the harmonization process with minor changes to promote enforceability. EPA has elected to codify these new guidelines in part 799 so as to distinguish them from the pre-harmonization guidelines in 40 CFR parts 795 through 798.

These guidelines will be placed in a new subpart H of part 799. In addition, EPA plans to reserve additional subparts of part 799 for test guidelines, so that the structure of part 799 would be as follows:

- Subpart A—General Provisions
- Subpart B—Specific Chemical Test Rules
- Subpart C—Testing Consent Orders
- Subpart D—Multichemical Test Rules
- Subpart E—G [Reserved]
- Subpart H—Health Effects Test Guidelines

The TSCA test guidelines currently in 40 CFR parts 795 through 798 will be retained for so long as there exist test rules whose data reimbursement periods under TSCA section 4(c) have not expired and which cross-reference the guidelines.

This table identifies the TSCA test guideline number with its comparable OPPTS harmonized test guideline public draft.

TABLE 1.—TSCA Test Guidelines Cross-Referenced to the OPPTS Harmonized Test Guidelines

Guideline title	TSCA 40 CFR section	OPPTS harmonized test guideline (public draft)
TSCA acute inhalation toxicity with histopathology	799.9135	870.1350
TSCA subchronic inhalation toxicity	799.9346	870.3465
TSCA prenatal developmental toxicity	799.9370	870.3700
TSCA reproduction and fertility effects	799.9380	870.3800
TSCA carcinogenicity	799.9420	870.4200
TSCA bacterial reverse mutation test	1799.9510	1OECD 471 and 472
TSCA in vitro mammalian cell gene mutation test	1799.9530	1OECD 476
TSCA mammalian bone marrow chromosomal aberration test	1799.9538	1OECD 475
TSCA mammalian erythrocyte micronucleus test	1799.9539	1OECD 474
TSCA neurotoxicity screening battery	799.9620	870.6200
TSCA immunotoxicity	799.9780	870.7800

¹The four TSCA genetic toxicity testing guidelines were adopted from the OECD guideline series and not the OPPTS public drafts.

Codification of these guidelines does not itself impose any obligations on any person. Obligations are imposed only when the guidelines are cross-referenced in individual TSCA section 4 rulemakings. When cross-referenced in such test rules, the pertinent TSCA guidelines serve as test standards for only these particular section 4 rules. EPA may propose modifications to the various guidelines as they are utilized for chemical-specific test rules. In each chemical-specific test rule, the proposed

test standards and any modifications thereto will be subject to public notice and comment.

V. Guideline by Guideline Discussion

In this unit is a summary of the significant changes made to the 11 harmonized guidelines proposed on June 20, 1996, which are being published in this document.

A. Section 799.9135 TSCA Acute Inhalation Toxicity with Histopathology

1. EPA dropped the requirement for a 1-hour (hr) exposure test. The Agency recognizes that such a technically difficult test would not be likely to yield useful information due to complicating factors such as biological rhythms and inapplicability to insoluble or chemically inactive particulates. Instead, EPA is requiring a 4-hr exposure point with a trigger for an 8-hr exposure point. Test sponsors have

the option to extrapolate from shorter-term exposures.

2. EPA dropped the requirement for performing histopathology in all animals and substituted a triggered approach (wherein gross pathology will be performed only when the frequency and severity of adverse effects for dosed animals are greater than those for control animals in the study).

3. EPA dropped the requirement of a breathing zone purity determination as unnecessary since the Agency now believes that standard inhalation toxicology will provide the purity measurement of the test substances.

4. EPA requires only a single control group in some circumstances. If both 4- and 8-hr exposures are being conducted in the study, then there would be a single control at the 8-hr exposure provided adequate historical control data show no changes in histopathology or bronchoalveolar lavage between controls for these test periods. If the 8-hr exposure is being performed as a result of the 4-hr trigger, there would need to be control groups for both 4- and 8-hr exposure groups.

5. EPA redefined the test exposure to 4 hrs of exposure to the target concentration as defined by an average of plus or minus 5% for gases and plus or minus 11% for particles. This redefinition establishes exposure tolerances, which better assures known test concentration than the original provision which only allowed for test exposure after the test chamber reached equilibrium.

6. EPA now distinguishes air change requirements between nose-only exposure (300 milliliter (mL)/minutes (min)/animal) and whole-body exposure (at least 12 to 15 air changes per hr).

7. EPA changed its description of the respiratory histopathology requirements to ensure that inflated state and fixed pressure with infusion fixation are used to prepare the lungs for examination.

8. EPA added the requirement to specify the anatomical location where the four sections are to be taken for nasal histopathology.

B. Section 799.9346 TSCA Subchronic Inhalation Toxicity

1. EPA changed the terms used for certain weekly observations from "motor activity" to "level of activity" and from "grip strength" to "altered strength" to reinforce the point that these observations need not be automated.

2. "Dose" and "dose level" were changed to "concentration" and "dosing" was changed to "exposure" to reflect that this is an inhalation study.

C. Section 799.9370 TSCA Prenatal Developmental Toxicity

EPA made no significant changes to this guideline.

D. Section 799.9380 TSCA Reproduction and Fertility Effects

1. EPA added the requirement for a triggered quantitative evaluation of primordial follicles from qualitative evidence of a possible treatment-related effect. While the Agency recognizes that there are issues concerning the validity of existing methods used to screen ovarian-primordial follicle counts, the Agency believes that the necessity to identify early senescence in females outweighs these concerns. EPA considers data about the effects of chemical substances on effects such as early female senescence to be essential to protecting human health.

2. EPA reduced the requirement for taking organ weights for pups already opened for necropsy. The guideline only requires organ weight data from one randomly selected pup/sex/litter rather than the three pups specified in the public draft. The Agency believes that collection of organ weight data from one pup/sex/litter rather than three will reduce burdens without compromising the ability to detect a treatment-related effect on brain, spleen, or thymus weight. The random selection is to be made from the population of pups already opened for necropsy.

3. EPA reduced the requirement that 20 adult animals per sex per exposure group be examined for histopathology to 10 animals (randomly chosen) per sex per exposure group. This reduction was made because there would be little additional statistical value in examining more than 10 animals per sex per group. Since the guideline still requires that gross necropsy and organ weight data be collected for all parental animals and that the weighed organs be preserved, questions about interpretation of marginal histopathological effects can be resolved by evaluation of the tissues from these animals.

4. EPA dropped the requirement of histopathology of developmental anomalies observed macroscopically in F1 and F2 weanlings. Since the intent of this requirement was to confirm the nature of the lesions already identified macroscopically, the Agency believes that the added value of the information would not be worth the cost of the evaluation.

E. Section 799.9420 TSCA Carcinogenicity

1. EPA revised the guideline to allow 5-day per week dosing for both gavage

and capsule administration. This change was made to eliminate the disparity between the original 7-day specification for capsules and 5 days for gavage since there was no justification for this disparity.

2. EPA changed the terms used for certain weekly observations from "motor activity" to "level of activity" and from "grip strength" to "altered strength" to reinforce the point that these observations need not be automated.

3. The requirement for the immunotoxicity screen has been deleted. The Agency agreed that the immunotoxicity screen conducted at study termination would provide little meaningful information on the potential toxicity of the chemical on the immune function system due to the geriatric changes in the animals.

4. EPA deleted the requirement for the weighing of spleens because their weight would be unacceptably variable due to the amount of blood lost during the exsanguination process. (The weighing of spleens is still a requirement in the immunotoxicity guideline).

F. Genetic Toxicity Testing

1. Section 799.9510 TSCA Bacterial Reverse Mutation Test.

2. Section 799.9530 TSCA In Vitro Mammalian Cell Gene Mutation Test.

3. Section 799.9538 TSCA Mammalian Bone Marrow Chromosomal Aberration Test.

4. Section 799.9539 TSCA Mammalian Erythrocyte Micronucleus Test.

EPA is incorporating these genetic toxicity guidelines directly from the OECD versions. The Agency made format changes in order to ensure consistency with the TSCA test guidelines format. The Agency actively participated in international discussions regarding the development of these guidelines. EPA participated in the review of the OECD drafts. EPA believes that because these OECD guidelines were developed with international scientific input through the OECD guideline development process, they provide state-of-the-art guidance which is equivalent to and more broadly accepted than that in the OPPTS harmonized test guidelines public drafts published on June 20, 1996. The process EPA used in developing the four TSCA genetic toxicity test guidelines is described in reference 5 of Unit VI. of this preamble.

G. Section 799.9620 TSCA Neurotoxicity Screening Battery

EPA made no significant changes to the public draft of this guideline although EPA made two clarifications to address SAP concerns. Clarifications to the positive control treatment were made to indicate that such testing need not be done as frequently as every 12 months. Examples were eliminated to clarify EPA's position that permanently injurious chemicals are not necessary, though EPA continues to believe that chemical exposures are appropriate

H. Section 799.9780 TSCA Immunotoxicity

1. EPA incorporated the recommendation of the SAP that the requirement for flow cytometric analysis of lymphocyte and Natural Killer (NK) cell phenotypes be eliminated. A test for the primary antibody (IgM) response to sheep red blood cell (PFC) or enzyme linked immunosorbent assay (ELISA) would still be required. The guideline now sets the required exposure time for the anti-sheep red blood cells (SRBC) assay at 28 days, thus providing information on the effects of the test material on non-specific immunity.

2. EPA adopted the SAP recommendation to delete the "optional immunotoxicity screen" because lymphocyte phenotyping by flow cytometry should be an option.

3. EPA added the requirement that appropriate species-specific monoclonal antibodies be used in the phenotyping assay. The Agency accepts the SAP recommendation that this will allow sufficient flexibility to allow for future advances in flow cytometry and antibody marker technology.

4. EPA adopted the SAP recommendation that a minimum of eight animals per treatment group be used in order to yield a sufficient statistical power to detect a 20% change based upon the inter-animal variation usually encountered in these assays.

5. EPA added the intraperitoneal route of exposure to the guideline in response to the SAP comment that this is an acceptable method for immunization with SRBCs.

6. EPA adopted the SAP recommendation that testing laboratories need not perform a positive control after every experiment. Instead, it is sufficient to include this control every 6 months or whenever new reagents are titrated.

VI. Public Record

The official record for this rulemaking, as well as the public version, has been established for this

rulemaking under docket control number OPPTS-42193 (including comments and data submitted electronically). This record contains the basic information considered by EPA in developing this rule. EPA will supplement this record as necessary.

A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as Confidential Business Information (CBI), is available for inspection from 12 noon to 4 p.m., Monday through Friday, except legal holidays. The public record is located in the TSCA Nonconfidential Information Center, Rm. NE-B607, 401 M St., SW., Washington, DC 20460.

The record includes the following information:

1. Public drafts of seven OPPTS harmonized health effects guidelines.

2. Four OECD genetic toxicity test guidelines.

3. References contained in TSCA health effects test guidelines promulgated in this document.

4. Final report of the FIFRA Scientific Advisory Panel meeting, held October 29-30, 1996.

5. USEPA. Memorandum, Angela Auletta to Roger Nelson. HAPs Rule: OECD Process for Update of Genetic Toxicity Test Guidelines. March 10, 1997.

VII. Regulatory Assessment Requirements

A. Waiver of Notice of Proposed Rulemaking and Delay in Effective Date

Because the test guidelines codified in this document have no substantive effect on any person without further rulemaking, and such rulemaking would be conducted under public notice and comment procedures, EPA finds that public notice and comment are unnecessary for this action. Thus, this rule may be promulgated without prior opportunity for public notice and comment, pursuant to the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B), and may be made effective immediately, without a 30-day delay, pursuant to 5 U.S.C. 553(d)(3).

B. Executive Order 12866, Executive Order 12898, and Executive Order 13045

This action is not subject to Executive Order 12866 (58 FR 51735, October 4, 1993) since, as explained in Units I. and IV. of this preamble, the guidelines are not intended to have the force and effect of law until they are cross-referenced in future test rules through public notice and comment procedures that establish those rules. For the same reason, this

action is not considered under Executive Order 12898 (59 FR 7629, February 16, 1994) as having a disproportionately high and adverse human health or environmental effect on minority populations and low-income populations. In addition, the action is not subject to Executive Order 13045 "Protection of Children From Environmental Health Risks and Safety Risk" (62 FR 19885, April 23, 1997) since it is neither economically significant under Executive Order 12866 nor does it concern an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children.

C. Paperwork Reduction Act

This rule does not contain information collection requirements that necessitate the approval of OMB under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

D. Regulatory Flexibility Act

The guidelines codified in this document do not constitute a rule for which EPA must publish a general notice of proposed rulemaking under 5 U.S.C. 553(b). Therefore, sections 603 and 604 of the Regulatory Flexibility Act, 5 U.S.C. 603 and 604 do not apply to this action.

E. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104-4, which establishes requirements for Federal agencies to assess the effects of certain regulatory actions on State, local, and tribal governments and the private sector, does not apply. This action contains neither a private sector nor an intergovernmental mandate because it does not impose an enforceable duty on anyone. Furthermore, a written statement is not required under section 202 of UMRA because section 202 only applies to rules for which a general notice of proposed rulemaking was published, and no such notice was issued for this rule.

F. Submission to Congress and the General Accounting Office

This action is not a major rule as defined by 5 U.S.C. 804(2). Pursuant to 5 U.S.C. 801(a)(1)(A), EPA has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to its publication in today's **Federal Register**.

List of Subjects in 40 CFR Part 799

Environmental protection, Chemicals, Hazardous substances, Health, Reporting and recordkeeping requirements.

Dated: August 7, 1997.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

Therefore, 40 CFR part 799 is amended as follows:

PART 799—[AMENDED]

1. The authority citation for part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

2. By adding a new paragraph (d) to § 799.1 to read as follows:

§ 799.1 Scope and purpose.

* * * * *

(d) This part contains certain TSCA test guidelines which are cross-referenced in the test rules contained in this part.

3. By adding and reserving subparts E through G.

4. By adding a new subpart H, consisting of § § 799.9135–799.9780, to read as follows:

Subpart H—Health Effects Test Guidelines

- 799.9135 TSCA acute inhalation toxicity with histopathology.
- 799.9346 TSCA subchronic inhalation toxicity.
- 799.9370 TSCA prenatal developmental toxicity.
- 799.9380 TSCA reproduction and fertility effects.
- 799.9420 TSCA carcinogenicity.
- 799.9510 TSCA bacterial reverse mutation test.
- 799.9530 TSCA in vitro mammalian cell gene mutation test.
- 799.9538 TSCA mammalian bone marrow chromosomal aberration test.
- 799.9539 TSCA mammalian erythrocyte micronucleus test.
- 799.9620 TSCA neurotoxicity screening battery.
- 799.9780 TSCA immunotoxicity.

Subpart H—Health Effects Test Guidelines**§ 799.9135 TSCA acute inhalation toxicity with histopathology.**

(a) *Scope.* This section is intended to meet the testing requirements under section 4 of the Toxic Substances Control Act (TSCA). In the assessment and evaluation of the potential human health effects of chemical substances, it is appropriate to test for acute inhalation toxic effects. The goals of this test are to characterize the exposure-

response relationship for sensitive endpoints following acute exposure and to characterize toxicologic response following acute high exposures. The latter is of particular concern in relation to spills and other accidental releases. This testing is designed to determine the gross pathology and histopathology resulting from acute inhalation exposure to a substance. Because toxic effects on the respiratory tract are of particular concern following inhalation exposure, several indicators of respiratory toxicity consisting of histopathology on fixed tissue and evaluation of cellular and biochemical parameters in bronchoalveolar lavage fluid should be employed. The respiratory histopathology consists of specialized techniques to preserve tissues of the respiratory tract in order to allow detailed microscopic examination to identify adverse effects of chemical substances on this organ system. The bronchoalveolar lavage is designed to be a rapid screening test to provide an early indicator of pulmonary toxicity by examining biochemical and cytologic endpoints of material from the lungs of animals exposed to potentially toxic chemical substances. These acute tests are designed to assess the relationship, if any, between the animals' exposure to the test substance and to demonstrate relationship between the animals' exposure and the incidence and severity of observed abnormalities, including gross or histopathologic lesions, body weight changes, effects on mortality, and any other toxic effects. These acute tests are not intended to provide a complete evaluation of the toxicologic effects of a substance, and additional functional and morphological evaluations may be necessary to assess completely the potential effects produced by a chemical substance. Additional tests may include longer-term exposures, or more in-depth evaluation of specific organ systems as indicated by signs of toxicity following acute exposure.

(b) *Source.* This a new section developed by the United States Environmental Protection Agency.

(c) *Definitions.* The following definitions apply to this section.

Aerodynamic diameter (d_{ae}) refers to the size of particles. It is the diameter of a sphere of unit density that behaves aerodynamically (has the same settling velocity in air) as the particle of the test substance. It is used to compare particles of different size, shape, and density, and to predict where in the respiratory tract such particles may be primarily deposited.

Exposure response is the relationship between the exposure concentration and

the measured toxic response, whether expressed as a group mean ($\pm$ standard deviation) in the case of a continuous variable or as incidence in the case of a quantal variable. This definition should not preclude the exploration of other dose metrics in establishing this relationship.

Geometric standard deviation (GSD) is a dimensionless number equal to the ratio between the mass median aerodynamic diameter (MMAD) and either 84% or 16% of the diameter size distribution (e.g., MMAD = 2 μ m; 84% = 4 μ m; GSD = $4/2 = 2.0$.) The MMAD, together with the GSD, describe the particle size distribution of an aerosol. Use of the GSD may not be valid for non-lognormally distributed aerosols. (If the size distribution deviates from the lognormal, it shall be noted).

Inhalability is the ratio of the number concentration of particles of a certain aerodynamic diameter, d_{ae} , that are inspired through the nose or mouth to the number concentration of the same d_{ae} present in the inspired volume of ambient air. In humans, inhalability can exceed 15 μ m d_{ae} , whereas inhalability dramatically decreases for particles above 4 μ m d_{ae} in small laboratory animals.

Lower respiratory tract consists of those structures of the respiratory tract below the larynx.

Mass geometric mean aerodynamic diameter or the mass median aerodynamic diameter (MMAD) is the calculated aerodynamic diameter that divides the particles of an aerosol (a gaseous suspension of fine liquid or solid particles) in half, based on the weight of the particles. By weight, 50% of the particles will be larger than the MMAD and 50% of the particles will be smaller than the MMAD.

Particle regional deposition is the fraction of inhaled particles that deposits in the specific region of the respiratory tract. The major mechanisms of particle deposition in the respiratory tract include impaction, sedimentation, diffusion, interception, and electrostatic precipitation. The deposition mechanism that is dominant for a given region depends on the respiratory tract architecture and ventilation rate of the species and the aerosol particle size and distribution. The respiratory tract in both humans and various experimental mammals can be divided into three regions on the basis of structure, size, and function:

(1) The extrathoracic region or upper respiratory tract that includes the nose, mouth, nasopharynx, oropharynx, laryngopharynx, and larynx.

(2) The tracheobronchial region that includes the trachea, bronchi, and

bronchioles (including the terminal bronchioles).

(3) The alveolar region that includes the respiratory bronchioles (if present in the species), alveolar ducts, alveolar sacs, and alveoli.

Respiratory effects are any adverse effects on the structure or functions of the respiratory system related to exposure to a chemical substance.

Target organ is any organ found to be a target of toxicity in the 4-hour (hr) high concentration group as a result of:

(1) The initial histopathologic examination (respiratory tract, liver, kidney, gross lesions); or

(2) The retrospective histopathologic examination of archived organs triggered by their identification as targets of toxicity in a 90-day study.

Toxic effects are any adverse changes (a change that is statistically and biologically significant) in the structure or function of an experimental animal as a result of exposure to a chemical substance.

Upper respiratory tract consists of those structures of the respiratory tract above and including the larynx.

(d) *Principle of the test method.* The test substance shall be administered to several groups of experimental animals; one concentration level and duration being used per group. Bronchoalveolar lavage shall be used to evaluate early effects on the respiratory system by examining changes in the content of the lavage fluid of the lung. At 24 hrs following exposure, the animals shall be sacrificed and necropsied, and tissue samples from the respiratory tract and other major organs will be prepared for microscopic examination. The exposure levels at which significant toxic effects on the respiratory organ system are produced are compared to those levels that produce other toxic effects. As triggered by the results of the 4-hr test, additional exposure periods of 1 hr and 8 hrs will be required to determine the effect of exposure time on the toxicity observed. A 1-hr exposure study can be elected as an option to provide data suitable for risk assessment for very short duration exposures as may occur from chemical releases. In the absence of adequate toxicological data for 1-hr exposure, the Agency will extrapolate to shorter-term exposures from the 4-hr data on the basis of concentration alone. This is a conservative method of extrapolation, consistent with general Agency methods for deriving criteria for short-term exposure from longer-term studies (a concentration x time extrapolation would result in higher concentration for a shorter duration).

(e) *Test procedures*—(1) *Animal selection*—(i) *Species.* In general, the

laboratory rat and mouse should be used. Under some circumstances, other species, such as the hamster or guinea pig, may be more appropriate, and if these or other species are used, justification should be provided.

(ii) *Strain.* If rats and mice are used, the use of the F344 rat and the B6C3F1 mouse is preferred to facilitate comparison with existing data.

(iii) *Age.* Young adults shall be used. The weight variation of animals used in a test should not exceed $\pm 20\%$ of the mean weight for each species.

(iv) *Sex.* Equal numbers of animals of each sex shall be used for each concentration level. The females shall be nulliparous and nonpregnant.

(v) *Health status.* Body weight and feed consumption are not sufficient indicators of the health status of animals prior to initiating an inhalation toxicity study. Prior to initiating the study, animals shall be monitored for known viral and bacterial respiratory pathogens determined by conventional microbiological assays (e.g., serology). The animals shall be free from pathogens at the start of exposure.

(2) *Number of animals.* At least five males and five females shall be used in each concentration/duration and control group. Animals shall be randomly assigned to treatment and control groups.

(3) *Control groups.* The control group shall be a sham-treated group. Except for treatment with the test substance, animals in the control group shall be handled in a manner identical to the test-group animals. Where a vehicle is used to help generate an appropriate concentration of the substance in the atmosphere, a vehicle control group shall be used. If the 4- and 8-hr exposure studies are conducted concurrently, a concurrent 8-hr sham-exposed control group may serve as the control group for both the 4-hr and the 8-hr exposure studies, provided there is adequate historical control data showing no changes in histopathology or bronchoalveolar lavage of controls exposed for 4 and 8 hrs. Similarly, if the optional 1-hr exposure study is conducted concurrently with the 4- and/or 8-hr study, the concurrent control group for those studies may also be used for the 1-hr study, provided adequate historical control data show no changes in histopathology or bronchoalveolar lavage between controls exposed for these time periods.

(4) *Concentration level and concentration selection.* For the 4-hr study, at least three concentrations shall be used in addition to the control group. Ideally, the data generated from the test should be sufficient to produce an

exposure-response curve. The concentrations can either be linearly or logarithmically spaced depending on the anticipated steepness of the concentration-response curve. A rationale for concentration selection should be provided to indicate that the selected concentrations will maximally support detection of concentration-response relationship. The high concentration should be clearly toxic or a limit concentration, but should not result in an incidence of fatalities that would preclude a meaningful evaluation of the data. The lowest concentration should define a no-observed-adverse-effects level (NOAEL).

(i) *Limit concentration.* For aerosols and particles, the high concentrations need not be greater than 2 mg/L, or concentrations that cannot maintain a particle size distribution having an MMAD between 1 and 4 μm (i.e., a particle size that permits inhalability and deposition throughout the respiratory tract). For fibers, the bivariate distribution of length and diameter must ensure inhalability. For gases and vapors, the concentrations need not be greater than 50,000 ppm or 50% of the lower explosive limit, whichever is lower. If a test at an aerosol or particulate exposure of 2 mg/L (actual concentration of respirable substance) for 4 hrs or, where this is not feasible, the maximum attainable concentration, using the procedures described for this study, produces no observable toxic effects, then a full study using three concentrations will not be necessary. Similarly, if a test at a gas or vapor exposure of 50,000 ppm or 50% of the lower explosive limit, whichever is lower, produces no observable toxic effects, then a full study using three concentrations will not be necessary.

(ii) *8-Hr study and optional 1-hr study.* If the 8-hr study is triggered, three concentrations shall be tested. These concentrations should allow for the determination of an effect level and a NOAEL. If the option to perform a 1-hr study is elected, three concentrations shall be selected and tested in a similar manner.

(5) *Inhalation exposure.* Animals can be exposed to the substance by either a nose-only procedure or in a whole-body exposure chamber.

(i) *Inhalation chambers.* The animals shall be tested in inhalation equipment designed to sustain a dynamic airflow for nose-only exposures of at least 300 ml/minute/animal or an airflow for whole-body exposures of at least 12 to 15 air changes per hr and ensure an adequate oxygen content of at least 19% and an evenly distributed exposure

atmosphere. Where a whole-body chamber is used, its design shall minimize crowding by providing individual caging. As a general rule, to ensure stability of a chamber atmosphere, the total "volume" of the test animals should not exceed 5% of the volume of the test chamber.

(ii) *Environmental conditions.* The temperature at which the test is performed shall be maintained at 22 °C (± 2 °C). Ideally, the relative humidity should be maintained between 40% and 60%, but in certain instances (e.g., tests using water as a vehicle), this may not be practical.

(iii) *Exposure periodicity.* For acute testing, the exposure design shall enable 4 hrs of exposure to the target concentrations, as defined by an average of $\pm 5\%$ for gases and vapors and $\pm 15\%$ for particles and aerosols. If triggered by the results of the 4-hr exposure, additional testing shall be conducted in a comparable manner using an 8-hr exposure period.

(6) *Physical measurements.*

Measurements or monitoring shall be made of the following:

(i) Chemical purity of the test material shall be analyzed.

(ii) The rate of airflow shall be monitored continuously, but shall be recorded at least every 30 minutes.

(iii) The actual concentrations of the test substance shall be measured in the breathing zone. During the exposure period, the actual concentrations of the test substance shall be held as constant as practical, monitored continuously or intermittently depending on the method of analysis, and recorded at least at the beginning, at an intermediate time, and at the end of the exposure period. Well-established and published monitoring methods should be used where available. If no standard methods are available, then accuracy and precision information must be supplied.

(iv) During the development of the generating system, appropriate particle size analysis shall be performed to establish the stability of the aerosol. During exposure, analysis should be conducted as often as necessary to determine the consistency of particle size distribution. The particle size distribution shall have an MMAD between 1 and 4 μm . The particle size of hygroscopic materials shall be small enough when dry to assure that the size of the particle at saturation will still have an MMAD between 1 and 4 μm . Characterization for fibers shall include the bivariate distribution of length and diameter; this distribution must ensure inhalability.

(v) If the test substance is present in a mixture, the mass and composition of

the entire mixture, as well as the principal compound, shall be measured.

(vi) Temperature and humidity shall be monitored continuously, but shall be recorded at least every 30 minutes.

(7) *Food and water during exposure period.* Food shall be withheld during exposure. Water may also be withheld in certain cases.

(8) *Observation period.* The bronchoalveolar lavage and respiratory pathology shall be conducted 24 hrs following exposure to allow expression of signs of toxicity. There is concern that some latency time will be required to allow migration of cells and macromolecules into the lungs following exposure, and that some pathology may require macromolecular synthesis or degradation before cell damage develops.

(9) *Gross pathology.* (i) All animals shall be subjected to a full gross necropsy which includes examination of orifices and the cranial, thoracic, and abdominal cavities and their contents.

(ii) At least the lungs, liver, kidneys, adrenals, brain, and gonads shall be weighed wet, as soon as possible after dissection to avoid drying.

(iii) The following organs and tissues, or representative samples thereof, shall be preserved in a suitable medium for possible future histopathological examination: All gross lesions; brain-including sections of medulla/pons; cerebellar cortex and cerebral cortex; pituitary; thyroid/parathyroid; thymus; heart; sternum with bone marrow; salivary glands; liver; spleen; kidneys; adrenals; pancreas; gonads; accessory genital organs (epididymis, prostrate, and, if present, seminal vesicles); aorta; skin; gall bladder (if present); esophagus; stomach; duodenum; jejunum; ileum; cecum; colon; rectum; urinary bladder; representative lymph nodes; thigh musculature; peripheral nerve; spinal cord at three levels cervical, midthoracic, and lumbar; and eyes. Respiratory tract tissues shall also be preserved in a suitable medium.

(10) *Histopathology.* The following histopathology shall be performed:

(i) Full histopathology shall be performed on the respiratory tract, liver and kidney of all animals in the control and high concentration groups. The histopathology of the respiratory tract is described under paragraph (e)(11) of this section.

(ii) All gross lesions which differ from controls in frequency, distribution, type, or severity in all concentration groups.

(iii) Target organs in all animals, as indicated by the observations in the high concentration group in this study. Histopathologic examination of target organs in animals at all concentration

levels (rather than only to the extent necessary to define the NOAEL) can support the application of exposure-response analyses such as the benchmark concentration approach.

(iv) Archived organs identified as targets of toxicity from results of the 90-day study (if a 90-day study is required for this substance) should be elevated in high concentration animals of the 4-hr acute study to determine if they are also targets of acute toxicity.

(11) *Respiratory tract histopathology.*

(i) Representative sections of the respiratory tract shall be examined histologically. These shall include the trachea, major conducting airways, alveolar region, terminal and respiratory bronchioles (if present), alveolar ducts and sacs, and interstitial tissues.

(ii) Care shall be taken that the method used to kill the animal does not result in damage to the tissues of the upper or lower respiratory tract. The lungs shall be infused with a fixative while in an inflated state of fixed pressure.

(iii) The upper respiratory tract shall be examined for histopathologic lesions. This examination shall use a minimum of four sections located as specified under paragraphs (e)(11)(iii)(A) through (e)(11)(iii)(D) of this section. An evaluation of the nasal vestibule shall be conducted. The method described by the reference under paragraph (h)(11) of this section should be given consideration. The use of additional sections shall be left to the discretion of the study pathologist, but consideration should be given to additional sections as recommended in the reference under paragraph (h)(8) of this section to ensure adequate evaluation of the entire upper respiratory tract, particularly the nasopharyngeal meatus. The following transverse sections shall be examined:

(A) Immediately posterior to the upper incisor teeth.

(B) At the incisor papilla.

(C) At the second palatal ridge.

(D) At the level of the first upper molar teeth.

(iv) The laryngeal mucosa shall be examined for histopathologic changes. Sections of the larynx to be examined include the epithelium covering the base of the epiglottis, the ventral pouch, and the medial surfaces of the vocal processes of the arytenoid cartilages.

(12) *Bronchoalveolar lavage.* (i) Animals can be exposed to the substance by either a nose-only procedure or in a whole-body exposure chamber.

(ii) Care should be taken that the method used to kill the animal results in minimum changes in the fluid of the lungs of the test animals.

(iii) At the appropriate time, the test animals shall be killed and the heart-lung including trachea removed in bloc. Alternatively, lungs can be lavaged in situ. If the study will not be compromised, one lobe of the lungs may be used for lung lavage while the other is fixed for histologic evaluation. The lungs should be lavaged using physiological saline. The lavages shall consist of two washes, each of which consists of approximately 80% (e.g., 5 ml in rats and 1 ml in mice) of the total lung volume. Additional washes merely tend to reduce the concentrations of the material collected. The lung lavage fluid shall be stored on ice at 5 °C until assayed.

(iv) The following parameters shall be determined in the lavage fluid as indicators of cellular damage in the lungs: total protein, cell count, and percent leukocytes. In addition, a phagocytosis assay shall be performed to determine macrophage activity. Assay methods described in the references under paragraphs (h)(1) and (h)(3) of this section may be used.

(13) *Combined protocol.* The tests described may be combined with any other toxicity study, as long as none of the requirements of either are violated by the combination.

(f) *Triggered testing.* If no adverse effects are seen in the 4-hr study as compared with controls, no further testing is necessary. If the 4-hr study shows positive effects in histopathology or the bronchoalveolar lavage, an 8-hr study shall be conducted. Only those tissues showing positive results in the 4-hr study must be pursued in the follow-up 8-hr study. Similarly, if the option to perform a 1-hr study is exercised, only those tissues showing positive results in the 4-hr study shall be pursued.

(g) *Data reporting and evaluation.* The final test report shall include the following information:

(1) *Description of equipment and test methods.* A description of the general design of the experiment and any equipment used shall be provided.

(i) Description of exposure apparatus, including design, type, dimensions, source of air, system for generating particles, aerosols, gasses, and vapors, method of conditioning air, treatment of exhaust air, and the method of housing animals in a test chamber.

(ii) Description of the equipment for measuring temperature, humidity, and particulate aerosol concentration and size.

(iii) Exposure data shall be tabulated and presented with mean values and measure of variability (e.g., standard deviation) and should include:

(A) Chemical purity of the test material.

(B) Airflow rates through the inhalation equipment.

(C) Temperature and humidity of air.

(D) Nominal concentration (total amount of test substance fed into the inhalation equipment divided by the volume of air).

(E) Actual concentration in test breathing zone.

(F) Particle size distribution (e.g., MMAD with GSD) and the bivariate distribution of fiber length and diameter, where appropriate.

(2) *Results*—(i) *General group animal data.* The following information shall be arranged by test group exposure level.

(A) Number of animals exposed.

(B) Number of animals dying.

(C) Number of animals showing overt signs of toxicity.

(D) Pre- and post-exposure body weight change in animals, and weight change during the observation period.

(ii) *Counts and incidence of gross alterations observed at necropsy in the test and control groups.* Data shall be tabulated to show:

(A) The number of animals used in each group and the number of animals in which any gross lesions were found.

(B) The number of animals affected by each different type of lesion, and the locations and frequency of each type of lesion.

(iii) *Counts and incidence of general histologic alterations in the test group.* Data shall be tabulated to show:

(A) The number of animals used in each group and the number of animals in which any histopathologic lesions were found.

(B) The number of animals affected by each different type of lesion, and the locations, frequency, and average grade of each type of lesion.

(iv) *Counts and incidence of respiratory histopathologic alterations by the test group.* Data shall be tabulated to show:

(A) The number of animals used in each group and the number of animals in which any histopathologic lesions were found.

(B) The number of animals affected by each different type of lesion, and the locations, frequency, and average grade of each type of lesion.

(v) *Results of the bronchoalveolar lavage study.* Data shall be tabulated to show:

(A) The amount of administered lavage fluid and recovered lavage fluid for each test animal.

(B) The magnitude of change of biochemical and cytologic indices in lavage fluids at each test concentration for each animal.

(C) Results shall be quantified as amount of constituent/mL of lavage fluid. This assumes that the amount of lavage fluid recovered is a representative sample of the total lavage fluid.

(3) *Evaluation of data.* The findings from this acute study should be evaluated in the context of preceding and/or concurrent toxicity studies and any correlated functional findings. The evaluation shall include the relationship between the concentrations of the test substance and the presence or absence, incidence, and severity of any effects. The evaluation should include appropriate statistical analyses, for example, parametric tests for continuous data and non-parametric tests for the remainder. Choice of analyses should consider tests appropriate to the experimental design, including repeated measures. The report must include concentration-response curves for the bronchoalveolar lavage and tables reporting observations at each concentration level for necropsy findings and gross, general, and respiratory system histopathology.

(h) *Reference.* For additional background information on this test guideline, the following references should be consulted. These references are available for inspection at the TSCA Nonconfidential Information Center, Rm. NE-B607, Environmental Protection Agency, 401 M St., SW., Washington, DC, 12 noon to 4 p.m., Monday through Friday, except legal holidays.

(1) Burleson, G.R., Fuller, L.B., Ménache, M.G., and Graham, J.A. Poly (I): poly (C)-enhanced alveolar peritoneal macrophage phagocytosis: Quantification by a new method utilizing fluorescent beads. *Proceedings of the Society of Experimental Biology and Medicine*. 184:468–476 (1987).

(2) Gardner, D.E., Crapo, J.D., and McClellan, R.O. (Eds.) *Toxicology of the Lung*. (Raven Press, New York, 1993) pp. i–xii, 1–30.

(3) Gilmour, G.I., and Selgrade, M.K. A comparison of the pulmonary defenses against streptococcal infection in rats and mice following O₃ exposure: Differences in disease susceptibility and neutrophil recruitment. *Toxicology and Applied Pharmacology*. 123:211–218 (1993).

(4) Henderson, R.F., Benson, J.M., Hahn, F.F., Hobbs, C.H., Jones, R.K., Mauderly, J.L., McClellan, R.O., and Pickrell, J.A. New approaches for the evaluation of pulmonary toxicity: Bronchoalveolar lavage fluid analysis. *Fundamental and Applied Toxicology*. 5:451–458 (1985).

(5) Henderson, R.F. Use of bronchoalveolar lavage to detect lung damage. *Environmental Health Perspectives*. 56:115–129 (1984).

(6) Henderson, R.F., Rebar, A.H., Pickrell, J.A., and Newton, G.J. Early damage indicators in the lung. III. Biochemical and cytological response of the lung to inhaled metal salts. *Toxicology and Applied Pharmacology*. 50:123–136 (1979).

(7) McClellan, R.O. and Henderson, R.F. (Eds.) Second edition. *Concepts in Inhalation Toxicology*. (Taylor and Francis, Washington, DC, 1995) pp.i–xxiv, 1–24, 441–470.

(8) Mery, S., Gross, E.A., Joyner, D.R., Godo, M., and Morgan, K.T. Nasal Diagrams: A Tool for Recording the Distribution of Nasal Lesions in Rats and Mice. *Toxicologic Pathology*. 22:353–372 (1994).

(9) Phalen, R.F. (Ed) *Methods in Inhalation Toxicology*. (CRC Press, Boca Raton, FL, 1997) pp. i–xii, 1–12.

(10) Renne, R.A., Gideon, K.M., Miller, R.A., Mellick, P.W., and Grumbein, S.L. Histologic methods and interspecies variations in the laryngeal histology of F344/N rats and B6C3F1 mice. *Toxicology and Pathology*. 20:44–51 (1992).

(11) Young, J.T. Histopathologic examination of the rat nasal cavity. *Fundamental and Applied Toxicology*. 1:309–312 (1981).

§ 799.9346 TSCA subchronic inhalation toxicity.

(a) *Scope* This section is intended to meet the testing requirements under section 4 of TSCA. In the assessment and evaluation of the toxic characteristics of a gas, volatile substance, or aerosol/particulate, determination of subchronic inhalation toxicity may be carried out after initial information on toxicity has been obtained by acute testing. The subchronic inhalation study has been designed to permit the determination of the no-observed-effect-level (NOEL) and toxic effects associated with continuous or repeated exposure to a test substance for a period of 90 days. This study is not capable of determining those effects that have a long latency period for development (e.g., carcinogenicity and life shortening). Extrapolation from the results of this study to humans is valid only to a limited degree. It can, however, provide useful information on health hazards likely to arise from repeated exposures by the inhalation route over a limited period of time. It will provide information on target organs and the possibilities of accumulation, and can be of use in selecting concentration levels for

chronic studies and establishing safety criteria for human exposure. Hazards of inhaled substances are influenced by the inherent toxicity and by physical factors such as volatility and particle size.

(b) *Source*. The source material used in developing this TSCA test guideline is the OPPTS harmonized test guideline 870.3465 (June 1996 Public Draft). This source is available at the address in paragraph (h) of this section.

(c) *Definitions*. The following definitions apply to this section.

Aerodynamic equivalent diameter is defined as the diameter of a unit density sphere having the same terminal settling velocity as the particle in question, whatever its size, shape, and density. It is used to predict where in the respiratory tract such particles may be deposited.

Concentration in a subchronic inhalation study is the amount of test substance administered via inhalation for a period of 90–days. Concentration is expressed as weight of the test substance per unit volume of air (milligrams per liter or parts per million).

Cumulative toxicity is the adverse effects of repeated exposures occurring as a result of prolonged action on, or increased concentration of the administered test substance or its metabolites in susceptible tissues.

Inhalable diameter refers to that aerodynamic diameter of a particle which is considered to be inhalable for the organism. It is used to refer to particles which are capable of being inhaled and may be deposited anywhere within the respiratory tract

Mass median aerodynamic diameter (MMAD) is the median aerodynamic diameter and along with the geometric standard deviation (GSD) is used to describe the particle size distribution of any aerosol statistically based on the weight and size of the particles. Fifty percent of the particles by weight will be smaller than the median diameter and 50% of the particles will be larger.

No-observed-effect-level (NOEL) is the maximum concentration used in a study which produces no adverse effects.

Subchronic inhalation toxicity is the adverse effects occurring as a result of the repeated daily exposure of experimental animals to a chemical by inhalation for part (approximately 10%) of a life span.

(d) *Limit test*. The exposure is at a concentration of 1 mg/L or greater (expected human exposure may indicate the need for a higher concentration), where such concentration is not possible due to physical or chemical properties of the test substance, or

where the maximum attainable concentration produces no observable toxic effects. A full study using three concentrations may not be necessary.

(e) *Test procedures*—(1) *Animal selection*—(i) *Species and strain*. A mammalian species shall be used for testing. A variety of rodent species may be used, although the rat is the preferred species. Commonly used laboratory strains should be employed. If another mammalian species is used, the tester shall provide justification/reasoning for its selection.

(ii) *Age/weight*. (A) Testing should be started with young healthy animals as soon as possible after weaning and acclimatization.

(B) Exposure shall commence no later than 8 weeks of age.

(C) At the commencement of the study the weight variation of animals used shall not exceed $\pm 20\%$ of the mean weight for each sex.

(iii) *Sex*. (A) Equal numbers of animals of each sex shall be used at each concentration.

(B) Females shall be nulliparous and nonpregnant.

(iv) *Numbers*. (A) At least 20 rodents (10 females and 10 males) should be used for each test group. If another mammalian species is selected (e.g. dog, rabbit, or nonhuman primate), at least eight animals per group (four males and four females) shall be used.

(B) If interim sacrifices are planned, the number of animals shall be increased by the number of animals scheduled to be sacrificed before the completion of the study.

(C) To avoid bias, the use of adequate randomization procedures for the proper allocation of animals to test and control groups is required.

(D) Each animal shall be assigned a unique identification number. Dead animals, their preserved organs and tissues, and microscopic slides shall be identified by reference to the animal's unique number.

(v) *Husbandry*. (A) Animals may be group-caged by sex, but the number of animals per cage must not interfere with clear observation of each animal. The biological properties of the test substance or toxic effects (e.g., morbidity, excitability) may indicate a need for individual caging. Animals must be housed individually in inhalation chambers during exposure to aerosols.

(B) The temperature of the experimental animal rooms should be at $22 \pm 3^\circ\text{C}$.

(C) The relative humidity of the experimental animal rooms should be 30–70%.

(D) Where lighting is artificial, the sequence should be 12 h light/12 h dark.

(E) Control and test animals should be fed from the same batch and lot. The feed should be analyzed to assure adequacy of nutritional requirements of the species tested and for impurities that might influence the outcome of the test. Animals should be fed and watered *ad libitum* with food replaced at least weekly. For nonrodents feeding should be at least daily and water *ad libitum*.

(F) The study should not be initiated until animals have been allowed a period of acclimatization/quarantine.

(2) *Control and test substances.* (i) Whenever it is necessary to formulate the test substance with a vehicle for aerosol generation, the vehicle ideally should not elicit toxic effects or substantially alter the chemical or toxicological properties of the test substance.

(ii) One lot of the test substance should be used, if possible throughout the duration of the study, and the research sample should be stored under conditions that maintain its purity and stability. Prior to the initiation of the study, there should be a characterization of the test substance, including the purity of the test substance and, if technically feasible, the name and quantities of unknown contaminants and impurities.

(3) *Control groups.* A concurrent control group is required. This group shall be an untreated or sham-treated control group. Except for treatment with the test substance, animals in the control group shall be handled in a manner identical to the test group animals. Where a vehicle other than water is used to generate a substance, a vehicle control group should be used. If the toxic properties of the vehicle are not known or cannot be made available, both untreated and vehicle control groups are required.

(4) *Satellite group.* A satellite group of 20 animals (10 animals per sex) may be treated with the high concentration level for 90 days and observed for reversibility, persistence, or delayed occurrence of toxic effects for a post-treatment period of appropriate length, normally not less than 28 days. In addition, a control group of 20 animals (10 animals of each sex) should be added to the satellite study.

(5) *Concentration levels and concentration selection.* (i) In subchronic toxicity tests, it is desirable to have a concentration-response relationship as well as a NOEL. Therefore, at least three concentration levels plus a control and, where appropriate, a vehicle control (corresponding to the concentration of

vehicle at the highest exposure level) shall be used. Concentrations should be spaced appropriately to produce test groups with a range of toxic effects. The data should be sufficient to produce a concentration-response curve.

(ii) The highest concentration should result in toxic effects but not produce an incidence of fatalities which would prevent a meaningful evaluation.

(iii) The intermediate concentrations should be spaced to produce a gradation of toxic effects.

(iv) The lowest concentration should produce no evidence of toxicity.

(v) In the case of potentially explosive test substances, care should be taken to avoid generating explosive concentrations.

(6) *Administration of the test substance.* Animals should be exposed to the test substance for 6 h per day on a 7-day per week basis for a period of at least 90 days. Based primarily on practical considerations, exposure for 6 h per day on a 5-day per week basis is acceptable.

(7) *Observation period.* The animals should be observed for a period of 90 days. Animals in the satellite group (if used) scheduled for follow-up observations should be kept for at least 28 days further without treatment to assess reversibility.

(8) *Exposure specifications.* (i) The animals shall be tested in dynamic inhalation equipment designed to sustain a minimum airflow of 10 air changes per hr, an adequate oxygen content of at least 19%, and uniform conditions throughout the exposure chamber. Maintenance of slight negative pressure inside the chamber will prevent leakage of the test substance into the surrounding areas. It is not normally necessary to measure chamber oxygen concentration if airflow is adequate.

(ii) The selection of a dynamic inhalation chamber should be appropriate for the test substance and test system. Where a whole body chamber is used to expose animals to an aerosol, individual housing must be used to minimize crowding of the test animals and maximize their exposure to the test substance. To ensure stability of a chamber atmosphere, the total volume occupied by the test animals shall not exceed 5% of the volume of the test chamber. It is recommended, but not required, that nose-only or head-only exposure be used for aerosol studies in order to minimize oral exposures due to animals licking compound off their fur. Heat stress should be minimized.

(iii) The temperature at which the test is performed should be maintained at 22 ± 2 °C. The relative humidity should

be maintained between 40 and 60%, but in certain instances (e.g., use of water vehicle) this may not be practicable.

(9) *Physical measurements.*

Measurements or monitoring shall be made of the following:

(i) The rate of airflow shall be monitored continuously but recorded at least three times during the exposure.

(ii) The actual concentrations of the test substance shall be measured in the animal's breathing zone. During the exposure period, the actual concentrations of the test substance shall be held as constant as practicable and monitored continuously or intermittently depending on the method of analysis. Chamber concentration may be measured using gravimetric or analytical methods as appropriate. If trial run measurements are reasonably consistent ($\pm 10\%$ for liquid, aerosol, gas, or vapor; $\pm 20\%$ for dry aerosol), then two measurements should be sufficient. If measurements are not consistent, three to four measurements should be taken. Whenever the test substance is a formulation, or it is necessary to formulate the test substance with a vehicle for aerosol generation, the analytical concentration must be reported for the total formulation, and not just for the active ingredient (AI). If, for example, a formulation contains 10% AI and 90% inerts, a chamber analytical limit concentration of 2 mg/L would consist of 0.2 mg/L of the AI. It is not necessary to analyze inert ingredients provided the mixture at the animal's breathing zone is analogous to the formulation; the grounds for this conclusion must be provided in the study report. If there is some difficulty in measuring chamber analytical concentration due to precipitation, nonhomogeneous mixtures, volatile components, or other factors, additional analyses of inert components may be necessary.

(iii) During the development of the generating system, particle size analysis shall be performed to establish the stability of aerosol concentrations with respect to particle size. The MMAD particle size range should be between 1–3 μm . The particle size of hygroscopic materials should be small enough when dry to assure that the size of the swollen particle will still be within the 1–3 μm range. Measurements of aerodynamic particle size in the animal's breathing zone should be measured during a trial run. If MMAD values for each exposure level are within 10% of each other, then two measurements during the exposures should be sufficient. If pretest measurements are not within 10% of each other, three to four measurements should be taken.

(iv) Temperature and humidity shall be monitored continuously and recorded at least three times during an exposure.

(10) *Feed and water during exposure period.* Feed shall be withheld during exposure. Water may also be withheld during exposure.

(11) *Observation of animals.* (i) During and following exposure, observations are made and recorded systematically; individual records should be maintained for each animal. It is not always possible to observe animals during exposure in a whole-body chamber.

(ii) Observations shall be made at least once each day for morbidity and mortality. Appropriate actions should be taken to minimize loss of animals to the study (e.g., Necropsy or refrigeration of those animals found dead and isolation or sacrifice of weak or moribund animals).

(iii) A careful clinical examination shall be made at least once weekly. Observations should be detailed and carefully recorded, preferably using explicitly defined scales. Observations should include, but not be limited to, evaluation of skin and fur, eyes and mucous membranes, respiratory and circulatory effects, autonomic effects such as salivation, central nervous system effects, including tremors and convulsions, changes in the level of activity, gait and posture, reactivity to handling or sensory stimuli, altered strength, and stereotypes or bizarre behavior (e.g., self-mutilation, walking backwards).

(iv) Signs of toxicity should be recorded as they are observed including the time of onset, degree and duration.

(v) Individual weights of animals shall be determined shortly before the test substance is administered, and weekly thereafter.

(vi) Food consumption shall also be determined weekly if abnormal body weight changes are observed.

(vii) Moribund animals should be removed and sacrificed when noticed and the time of death should be recorded as precisely as possible.

(viii) At termination, all survivors in the treatment groups shall be sacrificed.

(12) *Clinical pathology.* Hematology and clinical chemistry examinations shall be made on all animals, including controls, of each sex in each group for rodents and all animals when nonrodents are used as test animals. For rodents, the hematology and clinical chemistry parameters should be examined once prior to initiation of exposure and at terminal sacrifice. For nonrodents, the hematology and clinical chemistry parameters should be

examined once prior to initiation of exposure, at monthly intervals or midway through the test period and at termination.

(i) The recommended hematology parameters are: Hemoglobin and hematocrit concentrations, red blood cell count, white blood cell count, differential leukocyte count, platelet count, and a measure of clotting potential such as prothrombin time or thromboplastin time.

(ii) Clinical chemistry parameters which are considered appropriate to all studies are electrolyte balance, carbohydrate metabolism, and liver and kidney function. Other determinations which may be necessary for an adequate toxicological evaluation include analyses of lipids, hormones, acid/base balance, methemoglobin and cholinesterase activity. Additional clinical biochemistry may be employed where necessary to extend the investigation of observed effects. The selection of specific tests will be influenced by observations on the mode of action of the substance and signs of clinical toxicity. Suggested blood clinical chemistry determinations:

(A) Electrolytes.

(1) Calcium.

(2) Chloride.

(3) Magnesium.

(4) Inorganic phosphorus.

(5) Potassium.

(6) Sodium.

(B) Enzymes.

(1) Alkaline phosphatase.

(2) Alanine aminotransferase.

(3) Aspartate aminotransferase.

(4) Gamma glutamyl transferase.

(C) Other.

(1) Albumin.

(2) Blood creatinine.

(3) Blood urea nitrogen.

(4) Globulins.

(5) Glucose (fasting).

(6) Total bilirubin.

(7) Total cholesterol.

(8) Total serum protein.

(iii) Urinalysis is not recommended on a routine basis, but only when there is an indication based on expected or observed toxicity.

(13) *Ophthalmological examination.* Ophthalmological examinations shall be made on all animals prior to the administration of the test substance and on all high concentration and control groups at termination. If changes in the eyes are detected, all animals in the other concentration groups shall be examined.

(14) *Gross pathology.* (i) All animals shall be subjected to a full gross necropsy which includes examination of the external surface of the body, all orifices and the cranial, thoracic, and abdominal cavities and their contents.

(ii) At least the liver, kidneys, brain, and gonads shall be trimmed and weighed wet, as soon as possible after dissection to avoid drying.

(iii) The following organs and tissues, or representative samples thereof, shall be preserved in a suitable medium for possible future histopathological examination:

(A) Digestive system.

(1) Salivary glands.

(2) Esophagus.

(3) Stomach.

(4) Duodenum.

(5) Jejunum.

(6) Ileum.

(7) Cecum.

(8) Colon.

(9) Rectum.

(10) Liver.

(11) Pancreas.

(12) Gallbladder (dogs).

(B) Nervous system.

(1) Brain (multiple sections).

(2) Pituitary.

(3) Peripheral nerve(s).

(4) Spinal cord (three levels).

(5) Eyes (retina, optic nerve).

(C) Glandular system.

(1) Adrenals.

(2) Parathyroids.

(3) Thyroids.

(D) Respiratory system.

(1) Trachea.

(2) Lung.

(3) Pharynx.

(4) Larynx.

(5) Nose.

(E) Cardiovascular/hematopoietic system.

(1) Aorta (thoracic).

(2) Heart.

(3) Bone marrow.

(4) Lymph nodes.

(5) Spleen.

(6) Thymus.

(F) Urogenital system.

(1) Kidneys.

(2) Urinary bladder.

(3) Prostate.

(4) Testes.

(5) Epididymides.

(6) Seminal vesicle(s).

(7) Uterus.

(8) Ovaries.

(G) Other.

(1) Lacrimal gland.

(2) Mammary gland.

(3) Skin.

(4) Skeletal muscle.

(5) All gross lesions and masses.

(6) Sternum and/or femur.

(15) *Histopathology.* (i) The following histopathology shall be performed:

(A) Full histopathology on the respiratory tract and other organs and tissues, listed under paragraph (e)(15)(iii) of this section, of all animals in the control and high exposure groups

and all animals that died or were killed during the study.

(B) All gross lesions in all animals.

(C) Target organs in all animals.

(D) Lungs, liver and kidneys of all animals. Special attention to examination of the respiratory tract should be made for evidence of infection as this provides a convenient assessment of the state of health of the animals.

(E) When a satellite group is used, histopathology shall be performed on tissues and organs identified as showing effects in the treated groups.

(ii) If excessive early deaths or other problems occur in the high exposure group compromising the significance of the data, the next concentration should be examined for complete histopathology.

(iii) An attempt should be made to correlate gross observations with microscopic findings.

(iv) Tissues and organs designated for microscopic examination should be fixed in 10% buffered formalin or a recognized suitable fixative as soon as necropsy is performed and no less than 48 hrs prior to trimming. Tissues should be trimmed to a maximum thickness of 0.4 cm for processing.

(f) *Data and reporting*—(1) *Treatment of results*. (i) Data shall be summarized in tabular form, showing for each test group the number of animals at the start of the test, the number of animals showing lesions, the types of lesions, and the percentage of animals displaying each type of lesion.

(ii) All observed results (quantitative and qualitative) should be evaluated by an appropriate statistical method. Any generally accepted statistical method may be used; the statistical methods including significance criteria should be selected during the design of the study.

(2) *Evaluation of study results*. The findings of the subchronic inhalation toxicity study should be evaluated in conjunction with the findings of preceding studies and considered in terms of the observed toxic effects and the necropsy and histopathological findings. The evaluation will include the relationship between the concentration of the test substance and duration of exposure, and the presence or absence, the incidence and severity, of abnormalities, including behavioral and clinical abnormalities, gross lesions, identified target organs, body weight changes, effects on mortality and any other general or specific toxic effects. A properly conducted subchronic test should provide a satisfactory estimation of a no-effect level. It also can indicate the need for an additional longer-term

study and provide information on the selection of concentrations.

(3) *Test report*. In addition to reporting requirements specified under 40 CFR part 792, subpart J, the following specific information shall be reported. Both individual and summary data should be presented.

(i) Test substance characterization shall include:

(A) Chemical identification.

(B) Lot or batch number.

(C) Physical properties.

(D) Purity/impurities.

(E) Identification and composition of any vehicle used.

(ii) Test system information shall include:

(A) Species and strain of animals used and rationale for selection if other than that recommended.

(B) Age, sex, and body weight.

(C) Test environment including cage conditions, ambient temperature, humidity, and light/dark periods.

(iii) Test procedure information shall include:

(A) Method of randomization used.

(B) Full description of experimental design and procedure.

(C) Exposure regimen including concentration levels, methods, and volume.

(D) Description of test conditions; the following exposure conditions shall be reported:

(1) Description of exposure apparatus including design, type, volume, source of air, system for generating aerosols, method of conditioning air, treatment of exhaust air and the method of housing the animals in a test chamber.

(2) The equipment for measuring temperature, humidity, and particulate aerosol concentrations and size should be described.

(E) Exposure data shall be tabulated and presented with mean values and a measure of variability (e.g., standard deviation) and include:

(1) Airflow rates through the inhalation equipment.

(2) Temperature and humidity of air.

(3) Actual (analytical or gravimetric) concentration in the breathing zone.

(4) Nominal concentration (total amount of test substance fed into the inhalation equipment divided by volume of air).

(5) Particle size distribution, calculated mass median aerodynamic diameter (MMAD) and geometric standard deviation (GSD).

(6) Explanation as to why the desired chamber concentration and/or particle size could not be achieved (if applicable) and the efforts taken to comply with this aspect of the section.

(iv) Test results information shall include:

(A) *Group animal data*. Tabulation of toxic response data by species, strain, sex and exposure level for:

(1) Number of animals exposed.

(2) Number of animals showing signs of toxicity.

(3) Number of animals dying.

(B) *Individual animal data*. Data should be presented as summary (group mean) as well as for individual animals.

(1) Time of death during the study or whether animals survived to termination.

(2) Time of observation of each abnormal sign and its subsequent course.

(3) Body weight data.

(4) Feed consumption data, when collected.

(5) Results of ophthalmological examination, when performed.

(6) Results of hematological tests performed.

(7) Results of clinical chemistry tests performed.

(8) Results of urinalysis tests performed.

(9) Necropsy findings, including absolute and relative organ weight data.

(10) Detailed description of all histopathological findings.

(11) Statistical treatment of results, where appropriate.

(g) *Quality control*. A system shall be developed and maintained to assure and document adequate performance of laboratory staff and equipment. The study shall be conducted in compliance with 40 CFR Part 792—Good Laboratory Practice Standards.

(h) *References*. For additional background information on this test guideline, the following references should be consulted. These references are available for inspection at the TSCA Nonconfidential Information Center, Rm. NE-B607, Environmental Protection Agency, 401 M St., SW., Washington, DC, 12 noon to 4 p.m., Monday through Friday, except legal holidays.

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§ 799.9370 TSCA prenatal developmental toxicity.

(a) *Scope* This section is intended to meet the testing requirements under section 4 of TSCA. This guideline for developmental toxicity testing is designed to provide general information concerning the effects of exposure on the pregnant test animal and on the developing organism; this may include death, structural abnormalities, or altered growth and an assessment of maternal effects. For information on testing for functional deficiencies and other postnatal effects, the guidelines for the two-generation reproductive toxicity study and the developmental neurotoxicity study should be consulted.

(b) *Source*. The source material used in developing this TSCA test guideline is the OPPTS harmonized test guideline 870.3700 (February 1996 Public Draft). This source is available at the address in paragraph (h) of this section.

(c) *Good laboratory practice standards*. The study shall be conducted in compliance with 40 CFR Part 792—Good Laboratory Practice Standards.

(d) *Principle of the test method*. The test substance is administered to pregnant animals at least from implantation to one day prior to the expected day of parturition. Shortly before the expected date of delivery, the pregnant females are terminated, the uterine contents are examined, and the fetuses are processed for visceral and skeletal evaluation.

(e) *Test procedures*—(1) *Animal selection*—(i) *Species and strain*. It is recommended that testing be performed in the most relevant species, and that laboratory species and strains which are commonly used in prenatal developmental toxicity testing be employed. The preferred rodent species is the rat and the preferred non-rodent species is the rabbit.

(ii) *Age*. Young adult animals shall be used.

(iii) *Sex*. Nulliparous female animals shall be used at each dose level. Animals should be mated with males of the same species and strain, avoiding the mating of siblings, if parentage is known. Day 0 in the test is the day on which a vaginal plug and/or sperm are observed in the rodent or that insemination is performed or observed in the rabbit.

(iv) *Number of animals*. Each test and control group shall contain a sufficient

number of animals to yield approximately 20 animals with implantation sites at necropsy.

(2) *Administration of test and control substances*—(i) *Dose levels and dose selection*. (A) At least three-dose levels and a concurrent control shall be used. Healthy animals shall be randomly assigned to the control and treatment groups, in a manner which results in comparable mean body weight values among all groups. The dose levels should be spaced to produce a gradation of toxic effects. Unless limited by the physical/chemical nature or biological properties of the test substance, the highest dose shall be chosen with the aim to induce some developmental and/or maternal toxicity but not death or severe suffering. In the case of maternal mortality, this should not be more than approximately 10%. The intermediate dose levels should produce minimal observable toxic effects. The lowest dose level should not produce any evidence of either maternal or developmental toxicity (i.e., the no-observed-adverse-effect level, NOAEL) or should be at or near the limit of detection for the most sensitive endpoint. Two- or four-fold intervals are frequently optimal for spacing the dose levels, and the addition of a fourth test group is often preferable to using very large intervals (e.g., more than a factor of 10) between dosages.

(B) It is desirable that additional information on metabolism and pharmacokinetics of the test substance be available to demonstrate the adequacy of the dosing regimen. This information should be available prior to testing.

(C) The highest dose tested need not exceed 1,000 mg/kg/day by oral or dermal administration, or 2 mg/L (or the maximum attainable concentration) by inhalation, unless potential human exposure data indicate the need for higher doses. If a test performed at the limit dose level, using the procedures described for this study, produces no observable toxicity and if an effect would not be expected based upon data from structurally related compounds, then a full study using three-dose levels may not be considered necessary.

(ii) *Control group*. (A) A concurrent control group shall be used. This group shall be a sham-treated control group or a vehicle-control group if a vehicle is used in administering the test substance.

(B) The vehicle control group should receive the vehicle in the highest volume used.

(C) If a vehicle or other additive is used to facilitate dosing, consideration should be given to the following

characteristics: Effects on the absorption, distribution, metabolism, or retention of the test substance; effects on the chemical properties of the test substance which may alter its toxic characteristics; and effects on the food or water consumption or the nutritional status of the animals.

(iii) *Route of administration*. (A) The test substance or vehicle is usually administered orally by intubation.

(B) If another route of administration is used, for example, when the route of administration is based upon the principal route of potential human exposure, the tester shall provide justification and reasoning for its selection, and appropriate modifications may be necessary. Care should be taken to minimize stress on the maternal animals. For materials administered by inhalation, whole-body exposure is preferable to nose-only exposure due to the stress of restraint required for nose-only exposure.

(C) The test substance shall be administered at approximately the same time each day.

(D) When administered by gavage or dermal application, the dose to each animal shall be based on the most recent individual body weight determination.

(iv) *Dosing schedule*. At minimum, the test substance shall be administered daily from implantation to the day before cesarean section on the day prior to the expected day of parturition. Alternatively, if preliminary studies do not indicate a high potential for preimplantation loss, treatment may be extended to include the entire period of gestation, from fertilization to approximately 1 day prior to the expected day of termination.

(f) *Observation of animals*—(1) *Maternal*. (i) Each animal shall be observed at least once daily, considering the peak period of anticipated effects after dosing. Mortality, moribundity, pertinent behavioral changes, and all signs of overt toxicity shall be recorded at this cageside observation. In addition, thorough physical examinations shall be conducted at the same time maternal body weights are recorded.

(ii) Animals shall be weighed on day 0, at termination, and at least at 3-day intervals during the dosing period.

(iii) Food consumption shall be recorded on at least 3-day intervals, preferably on days when body weights are recorded.

(iv) (A) Females shall be terminated immediately prior to the expected day of delivery.

(B) Females showing signs of abortion or premature delivery prior to scheduled termination shall be killed

and subjected to a thorough macroscopic examination.

(v) At the time of termination or death during the study, the dam shall be examined macroscopically for any structural abnormalities or pathological changes which may have influenced the pregnancy. Evaluation of the dams during cesarean section and subsequent fetal analyses should be conducted without knowledge of treatment group in order to minimize bias.

(vi) (A) Immediately after termination or as soon as possible after death, the uteri shall be removed and the pregnancy status of the animals ascertained. Uteri that appear nongravid shall be further examined (e.g. by ammonium sulfide staining) to confirm the nonpregnant status.

(B) Each gravid uterus (with cervix) shall be weighed. Gravid uterine weights should not be obtained from dead animals if autolysis or decomposition has occurred.

(C) The number of corpora lutea shall be determined for pregnant animals.

(D) The uterine contents shall be examined for embryonic or fetal deaths and the number of viable fetuses. The degree of resorption shall be described in order to help estimate the relative time of death of the conceptus.

(2) *Fetal.* (i) The sex and body weight of each fetus shall be determined.

(ii) Each fetus shall be examined for external anomalies.

(iii) Fetuses shall be examined for skeletal and soft tissue anomalies (e.g. variations and malformations or other categories of anomalies as defined by the performing laboratory).

(A) For rodents, approximately one-half of each litter shall be prepared by standard techniques and examined for skeletal alterations, preferably bone and cartilage. The remainder shall be prepared and examined for soft tissue anomalies, using appropriate serial sectioning or gross dissection techniques. It is also acceptable to examine all fetuses by careful dissection for soft tissue anomalies followed by an examination for skeletal anomalies.

(B) For rabbits, all fetuses shall be examined for both soft tissue and skeletal alterations. The bodies of these fetuses should be evaluated by careful dissection for soft-tissue anomalies, followed by preparation and examination for skeletal anomalies. An adequate evaluation of the internal structures of the head, including the eyes, brain, nasal passages, and tongue, should be conducted for at least half of the fetuses.

(g) *Data and reporting*—(1) *Treatment of results.* Data shall be reported individually and summarized in tabular

form, showing for each test group the types of change and the number of dams, fetuses, and litters displaying each type of change.

(2) *Evaluation of study results.* The following shall be provided:

(i) Maternal and fetal test results, including an evaluation of the relationship, or lack thereof, between the exposure of the animals to the test substance and the incidence and severity of all findings.

(ii) Criteria used for categorizing fetal external, soft tissue, and skeletal anomalies.

(iii) When appropriate, historical control data to enhance interpretation of study results. Historical data (on litter incidence and fetal incidence within litter), when used, should be compiled, presented, and analyzed in an appropriate and relevant manner. In order to justify its use as an analytical tool, information such as the dates of study conduct, the strain and source of the animals, and the vehicle and route of administration should be included.

(iv) Statistical analysis of the study findings should include sufficient information on the method of analysis, so that an independent reviewer/statistician can reevaluate and reconstruct the analysis. In the evaluation of study data, the litter should be considered the basic unit of analysis.

(v) In any study which demonstrates an absence of toxic effects, further investigation to establish absorption and bioavailability of the test substance should be considered.

(3) *Test report.* In addition to the reporting requirements as specified under 40 CFR part 792, subpart J, the following specific information shall be reported. Both individual and summary data should be presented.

(i) Species and strain.

(ii) Maternal toxic response data by dose, including but not limited to:

(A) The number of animals at the start of the test, the number of animals surviving, the number pregnant, and the number aborting.

(B) Day of death during the study or whether animals survived to termination.

(C) Day of observation of each abnormal clinical sign and its subsequent course.

(D) Body weight and body weight change data, including body weight change adjusted for gravid uterine weight.

(E) Food consumption and, if applicable, water consumption data.

(F) Necropsy findings, including gravid uterine weight.

(iii) Developmental endpoints by dose for litters with implants, including:

(A) Corpora lutea counts.

(B) Implantation data, number and percent of live and dead fetuses, and resorptions (early and late).

(C) Pre- and postimplantation loss calculations.

(iv) Developmental endpoints by dose for litters with live fetuses, including:

(A) Number and percent of live offspring.

(B) Sex ratio.

(C) Fetal body weight data, preferably by sex and with sexes combined.

(D) External, soft tissue, and skeletal malformation and variation data. The total number and percent of fetuses and litters with any external, soft tissue, or skeletal alteration, as well as the types and incidences of individual anomalies, should be reported.

(v) The numbers used in calculating all percentages or indices.

(vi) Adequate statistical treatment of results.

(vii) A copy of the study protocol and any amendments should be included.

(h) *References.* For additional background information on this test guideline, the following references should be consulted. These references are available for inspection at the TSCA Nonconfidential Information Center, Rm. NE-B607, Environmental Protection Agency, 401 M St., SW., Washington, DC, 12 noon to 4 p.m., Monday through Friday, except legal holidays.

(1) Aliverti, V.L. *et al.* The extent of fetal ossification as an index of delayed development in teratogenicity studies in the rat. *Teratology*. 20:237–242 (1979).

(2) Barrow, M.V. and W.J. Taylor. A rapid method for detecting malformations in rat fetuses. *Journal of Morphology* 127:291–306 (1969).

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(4) Edwards, J.A. Ed. Woolam, D.H.M. The external development of the rabbit and rat embryo. Vol. 3. *Advances in Teratology* (Academic, NY, 1968).

(5) Fritz, H. Prenatal ossification in rabbits as indicative of fetal maturity. *Teratology*. 11:313–320 (1974).

(6) Fritz, H. and Hess, R. Ossification of the rat and mouse skeleton in the perinatal period. *Teratology*. 3:331–338 (1970).

(7) Gibson, J.P. *et al.* Use of the rabbit in teratogenicity studies. *Toxicology and Applied Pharmacology*. 9:398–408 (1966).

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(14) Marr, M.C. *et al.* Comparison of single and double staining for evaluation of skeletal development: the effects of ethylene glycol (EG) in CD rats. *Teratology*. 37:476 (1988).

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(18) Organisation for Economic Co-operation and Development, No. 414: Teratogenicity, Guideline for Testing of Chemicals. [C(83)44 (Final)] (1983).

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(22) Staples, R.E. and Schnell, V.L. Refinements in rapid clearing technique in the KOH—alizarin red S method for

fetal bone. *Stain Technology*. 39:61–63 (1964).

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(26) Whitaker, J. and Dix, D.M. Double-staining for rat foetus skeletons in teratological studies. *Laboratory Animals*. 13:309–310 (1979).

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§ 799.9380 TSCA reproduction and fertility effects.

(a) *Scope.* This section is intended to meet the testing requirements under section 4 of the TSCA. This section is for two-generation reproduction testing and is designed to provide general information concerning the effects of a test substance on the integrity and performance of the male and female reproductive systems, including gonadal function, the estrous cycle, mating behavior, conception, gestation, parturition, lactation, and weaning, and on the growth and development of the offspring. The study may also provide information about the effects of the test substance on neonatal morbidity, mortality, target organs in the offspring, and preliminary data on prenatal and postnatal developmental toxicity and serve as a guide for subsequent tests. Additionally, since the study design includes *in utero* as well as postnatal exposure, this study provides the opportunity to examine the susceptibility of the immature/neonatal animal.

(b) *Source.* The source material used in developing this TSCA test guideline is the OPPTS harmonized test guideline 870.3800 (February 1996 Public Draft). This source is available at the address in paragraph (g) of this section.

(c) *Good laboratory practice standards.* The study shall be conducted in compliance with 40 CFR Part 792—Good Laboratory Practice Standards.

(d) *Principle of the test method.* The test substance is administered to parental (P) animals prior to and during their mating, during the resultant pregnancies, and through the weaning of their F1 offspring. The substance is then administered to selected F1 offspring during their growth into adulthood, mating, and production of an F2 generation, until the F2 generation is weaned.

(e) *Test procedures—(1) Animal selection—(i) Species and strain.* The rat is the most commonly used species for testing. If another mammalian species is used, the tester shall provide justification/reasoning for its selection, and appropriate modifications will be necessary. Healthy parental animals, which have been acclimated to laboratory conditions for at least 5 days and have not been subjected to previous experimental procedures, should be used. Strains of low fecundity shall not be used.

(ii) *Age.* Parental (P) animals shall be 5 to 9 weeks old at the start of dosing. The animals of all test groups should be of uniform weight, age, and parity as nearly as practicable, and should be representative of the species and strain under study.

(iii) *Sex.* (A) For an adequate assessment of fertility, both males and females shall be studied.

(B) The females shall be nulliparous and nonpregnant.

(iv) *Number of animals.* Each control group shall contain a sufficient number of mating pairs to yield approximately 20 pregnant females. Each test group shall contain a similar number of mating pairs.

(v) *Identification of animals.* Each animal shall be assigned a unique identification number. For the P generation, this should be done before dosing starts. For the F1 generation, this should be done for animals selected for mating; in addition, records indicating the litter of origin shall be maintained for all selected F1 animals.

(2) *Administration of test and control substances—(i) Dose levels and dose selection.* (A) At least three-dose levels and a concurrent control shall be used. Healthy animals should be randomly assigned to the control and treatment groups, in a manner which results in comparable mean body weight values among all groups. The dose levels should be spaced to produce a gradation of toxic effects. Unless limited by the physical/chemical nature or biological properties of the test substance, the highest dose should be chosen with the aim to induce some reproductive and/or systemic toxicity but not death or severe suffering. In the case of parental

mortality, this should not be more than approximately 10%. The intermediate dose levels should produce minimal observable toxic effects. The lowest dose level should not produce any evidence of either systemic or reproductive toxicity (i.e., the no-observed-adverse-effect level, NOAEL) or should be at or near the limit of detection for the most sensitive endpoint. Two- or four-fold intervals are frequently optimal for spacing the dose levels, and the addition of a fourth test group is often preferable to using very large intervals (e.g., more than a factor of 10) between dosages.

(B) It is desirable that additional information on metabolism and pharmacokinetics of the test substance be available to demonstrate the adequacy of the dosing regimen. This information should be available prior to testing.

(C) The highest dose tested should not exceed 1,000 mg/kg/day (or 20,000 ppm in the diet), unless potential human exposure data indicate the need for higher doses. If a test performed at the limit dose level, using the procedures described for this study, produces no observable toxicity and if an effect would not be expected based upon data from structurally related compounds, then a full study using three dose levels may not be considered necessary.

(ii) *Control group.* (A) A concurrent control group shall be used. This group shall be an untreated or sham treated group or a vehicle-control group if a vehicle is used in administering the test substance.

(B) If a vehicle is used in administering the test substance, the control group shall receive the vehicle in the highest volume used.

(C) If a vehicle or other additive is used to facilitate dosing, consideration should be given to the following characteristics: Effects on the absorption, distribution, metabolism, or retention of the test substance; effects on the chemical properties of the test substance which may alter its toxic characteristics; and effects on the food or water consumption or the nutritional status of the animals.

(D) If a test substance is administered in the diet and causes reduced dietary intake or utilization, the use of a paired control group may be considered necessary.

(iii) *Route of administration.* (A) The test substance is usually administered by the oral route (diet, drinking water, or gavage).

(B) If administered by gavage or dermal application, the dosage administered to each animal prior to mating and during gestation and

lactation shall be based on the individual animal body weight and adjusted weekly at a minimum.

(C) If another route of administration is used, for example, when the route of administration is based upon the principal route of potential human exposure, the tester should provide justification and reasoning for its selection, and appropriate modifications may be necessary. Care should be taken to minimize stress on the maternal animals and their litters during gestation and lactation.

(D) All animals should be dosed by the same method during the appropriate experimental period.

(iv) *Dosing schedule.* (A) The animals should be dosed with the test substance on a 7-days-a-week basis.

(B) Daily dosing of the parental (P) males and females shall begin when they are 5 to 9 weeks old. Daily dosing of the F1 males and females shall begin at weaning. For both sexes (P and F1), dosing shall be continued for at least 10 weeks before the mating period.

(C) Daily dosing of the P and F1 males and females shall continue until termination.

(3) *Mating procedure—(i) Parental.*

(A) For each mating, each female shall be placed with a single randomly selected male from the same dose level (1:1 mating) until evidence of copulation is observed or either 3 estrous periods or 2 weeks has elapsed. Animals should be separated as soon as possible after evidence of copulation is observed. If mating has not occurred after 2 weeks or 3 estrous periods, the animals should be separated without further opportunity for mating. Mating pairs should be clearly identified in the data.

(B) Vaginal smears shall be collected daily and examined for all females during mating, until evidence of copulation is observed.

(C) Each day, the females shall be examined for presence of sperm or vaginal plugs. Day 0 of pregnancy is defined as the day a vaginal plug or sperm are found.

(ii) *F1 mating.* For mating the F1 offspring, at least one male and one female should be randomly selected from each litter for mating with another pup of the same dose level but different litter, to produce the F2 generation.

(iii) *Second mating.* In certain instances, such as poor reproductive performance in the controls, or in the event of treatment-related alterations in litter size, the adults may be remated to produce an F1b or F2b litter. If production of a second litter is deemed necessary in either generation, the dams should be remated approximately 1–2

weeks following weaning of the last F1a or F2a litter.

(iv) *Special housing.* After evidence of copulation, animals that are presumed to be pregnant shall be caged separately in delivery or maternity cages. Pregnant animals shall be provided with nesting materials when parturition is near.

(v) *Standardization of litter sizes.* (A) Animals should be allowed to litter normally and rear their offspring to weaning. Standardization of litter sizes is optional.

(B) If standardization is performed, the following procedure should be used. On day 4 after birth, the size of each litter may be adjusted by eliminating extra pups by random selection to yield, as nearly as possible, four males and four females per litter or five males and five females per litter. Selective elimination of pups, i.e. based upon body weight, is not appropriate. Whenever the number of male or female pups prevents having four (or five) of each sex per litter, partial adjustment (for example, five males and three females, or four males and six females) is acceptable. Adjustments are not appropriate for litters of eight pups or less.

(4) *Observation of animals—(i) Parental.*

(A) Throughout the test period, each animal shall be observed at least once daily, considering the peak period of anticipated effects after dosing. Mortality, moribundity, pertinent behavioral changes, signs of difficult or prolonged parturition, and all signs of overt toxicity shall be recorded at this cageside examination. In addition, thorough physical examinations should be conducted weekly on each animal.

(B) Parental animals (P and F1) shall be weighed on the first day of dosing and weekly thereafter. Parental females (P and F1) should be weighed at a minimum on approximately gestation days 0, 7, 14, and 21, and during lactation on the same days as the weighing of litters.

(C) During the premating and gestation periods, food consumption shall be measured weekly at a minimum. Water consumption should be measured weekly at a minimum if the test substance is administered in the water.

(D) Estrous cycle length and normality should be evaluated by vaginal smears for all P and F1 females during a minimum of 3 weeks prior to mating and throughout cohabitation; care should be taken to prevent the induction of pseudopregnancy.

(E) For all P and F1 males at termination, sperm from one testis and one epididymis shall be collected for

enumeration of homogenization-resistant spermatids and cauda epididymal sperm reserves, respectively. In addition, sperm from the cauda epididymis (or vas deferens) should be collected for evaluation of sperm motility and sperm morphology.

(1) The total number of homogenization-resistant testicular sperm and cauda epididymal sperm should be enumerated. The method described in the reference under paragraph (g)(8) of this section may be used. Cauda sperm reserves can be derived from the concentration and volume of sperm in the suspension used to complete the qualitative evaluations, and the number of sperm recovered by subsequent mincing and/or homogenizing of the remaining cauda tissue. Enumeration in only control and high-dose P and F1 males may be performed unless treatment-related effects are observed; in that case, the lower dose groups should also be evaluated.

(2) An evaluation of epididymal (or vas deferens) sperm motility should be performed. Sperm should be recovered while minimizing damage (the evaluation techniques as described in the reference under paragraph (g)(8) of this section may be used), and the percentage of progressively motile sperm should be determined either subjectively or objectively. For objective evaluations, an acceptable counting chamber of sufficient depth can be used to effectively combine the assessment of motility with sperm count and sperm morphology. When computer-assisted motion analysis is performed, the derivation of progressive motility relies on user-defined thresholds for average path velocity and straightness or linear index. If samples are videotaped, or images otherwise recorded, at the time of necropsy, subsequent analysis of only control and high-dose P and F1 males may be performed unless treatment-related effects are observed; in that case, the lower dose groups should also be evaluated. In the absence of a video or digital image, all samples in all treatment groups should be analyzed at necropsy.

(3) A morphological evaluation of an epididymal (or vas deferens) sperm sample shall be performed. Sperm (at least 200 per sample) should be examined as fixed, wet preparations (the techniques for such examinations is described in the references under paragraphs (g)(4) and (g)(8) of this section may be used) and classified as either normal (both head and midpiece/tail appear normal) or abnormal. Examples of morphologic sperm abnormalities would include fusion,

isolated heads, and misshapen heads and/or tails. Evaluation of only control and high-dose P and F1 males may be performed unless treatment-related effects are observed; in that case, the lower dose groups should also be evaluated.

(ii) *Offspring.* (A) Each litter should be examined as soon as possible after delivery (lactation day 0) to establish the number and sex of pups, stillbirths, live births, and the presence of gross anomalies. Pups found dead on day 0 should be examined for possible defects and cause of death.

(B) Live pups should be counted, sexed, and weighed individually at birth, or soon thereafter, at least on days 4, 7, 14, and 21 of lactation, at the time of vaginal patency or balanopreputial separation, and at termination.

(C) The age of vaginal opening and preputial separation should be determined for F1 weanlings selected for mating. If there is a treatment-related effect in F1 sex ratio or sexual maturation, anogenital distance should be measured on day 0 for all F2 pups.

(5) *Termination schedule.* (i) All P and F1 adult males and females should be terminated when they are no longer needed for assessment of reproductive effects.

(ii) F1 offspring not selected for mating and all F2 offspring should be terminated at comparable ages after weaning.

(6) *Gross necropsy.* (i) At the time of termination or death during the study, all parental animals (P and F1) and when litter size permits at least three pups per sex per litter from the unselected F1 weanlings and the F2 weanlings shall be examined macroscopically for any structural abnormalities or pathological changes. Special attention shall be paid to the organs of the reproductive system.

(ii) Dead pups or pups that are terminated in a moribund condition should be examined for possible defects and/or cause of death.

(iii) At the time of necropsy, a vaginal smear should be examined to determine the stage of the estrous cycle. The uteri of all cohoused females should be examined, in a manner which does not compromise histopathological evaluation, for the presence and number of implantation sites.

(7) *Organ weights.* (i) At the time of termination, the following organs of all P and F1 parental animals shall be weighed:

(A) Uterus (with oviducts and cervix), ovaries.

(B) Testes, epididymides (total weights for both and cauda weight for either one or both), seminal vesicles

(with coagulating glands and their fluids), and prostate.

(C) Brain, pituitary, liver, kidneys, adrenal glands, spleen, and known target organs.

(ii) For F1 and F2 weanlings that are examined macroscopically, the following organs shall be weighed for one randomly selected pup per sex per litter.

(A) Brain.

(B) Spleen and thymus.

(8) *Tissue preservation.* The following organs and tissues, or representative samples thereof, shall be fixed and stored in a suitable medium for histopathological examination.

(i) For the parental (P and F1) animals:

(A) Vagina, uterus with oviducts, cervix, and ovaries.

(B) One testis (preserved in Bouin's fixative or comparable preservative), one epididymis, seminal vesicles, prostate, and coagulating gland.

(C) Pituitary and adrenal glands.

(D) Target organs, when previously identified, from all P and F1 animals selected for mating.

(E) Grossly abnormal tissue.

(ii) For F1 and F2 weanlings selected for macroscopic examination: Grossly abnormal tissue and target organs, when known.

(9) *Histopathology*—(i) *Parental animals.* Full histopathology of the organs listed under paragraph (e)(8)(i) of this section shall be performed for ten randomly chosen high dose and control P and F1 animals per sex, for those animals that were selected for mating. Organs demonstrating treatment-related changes shall also be examined for the remainder of the high-dose and control animals and for all parental animals in the low- and mid-dose groups. Additionally, reproductive organs of the low- and mid-dose animals suspected of reduced fertility, e.g., those that failed to mate, conceive, sire, or deliver healthy offspring, or for which estrous cyclicity or sperm number, motility, or morphology were affected, shall be subjected to histopathological evaluation. Besides gross lesions such as atrophy or tumors, testicular histopathological examination should be conducted in order to identify treatment-related effects such as retained spermatids, missing germ cell layers or types, multinucleated giant cells, or sloughing of spermatogenic cells into the lumen. Examination of the intact epididymis should include the caput, corpus, and cauda, which can be accomplished by evaluation of a longitudinal section, and should be conducted in order to identify such lesions as sperm granulomas, leukocytic

infiltration (inflammation), aberrant cell types within the lumen, or the absence of clear cells in the cauda epididymal epithelium. The postlactational ovary should contain primordial and growing follicles as well as the large corpora lutea of lactation. Histopathological examination should detect qualitative depletion of the primordial follicle population. A quantitative evaluation of primordial follicles should be conducted for all F1 females if any of the following treatment-related findings were observed:

(A) Reductions in ovarian weight and abnormal ovarian histopathology findings, e.g., follicular cysts or qualitative evidence of a reduced population of primordial follicles.

(B) Abnormal estrous cyclicity and female infertility.

(C) Depletion of testicular spermatid counts in F1 males and evidence of germ cell depletion in testicular histopathology evaluations.

(ii) *Examination of ovarian sections.* If a quantitative evaluation is performed, ten ovarian sections shall be taken at least 100 μ m apart from the inner third of each ovary. Examination should include enumeration of the total number of primordial and antral follicles from these 20 sections (the technique for this histological assessment as described in the reference under paragraph (g)(2) of this section may be used) for comparison with control ovaries.

(iii) *Weanlings.* For F1 and F2 weanlings, histopathological examination of treatment-related abnormalities noted at macroscopic examination should be considered, if such evaluation were deemed appropriate and would contribute to the interpretation of the study data.

(f) *Data and reporting—(1) Treatment of results.* Data shall be reported individually and summarized in tabular form, showing for each test group the types of change and the number of animals displaying each type of change.

(2) *Evaluation of study results.* (i) An evaluation of test results, including the statistical analysis, shall be provided. This should include an evaluation of the relationship, or lack thereof, between the exposure of the animals to the test substance and the incidence and severity of all abnormalities.

(ii) When appropriate, historical control data should be used to enhance interpretation of study results. Historical data, when used, should be compiled, presented, and analyzed in an appropriate and relevant manner. In order to justify its use as an analytical tool, information such as the dates of study conduct, the strain and source of

the animals, and the vehicle and route of administration should be included.

(iii) Statistical analysis of the study findings should include sufficient information on the method of analysis, so that an independent reviewer/statistician can reevaluate and reconstruct the analysis.

(iv) In any study which demonstrates an absence of toxic effects, further investigation to establish absorption and bioavailability of the test substance should be considered.

(3) *Test report.* In addition to the reporting requirements as specified under 40 CFR part 792, subpart J, the following specific information shall be reported. Both individual and summary data should be presented.

(i) Species and strain.

(ii) Toxic response data by sex and dose, including indices of mating, fertility, gestation, birth, viability, and lactation; offspring sex ratio; precoital interval, including the number of days until mating and the number of estrous periods until mating; and duration of gestation calculated from day 0 of pregnancy. The report should provide the numbers used in calculating all indices.

(iii) Day (week) of death during the study or whether animals survived to termination; date (age) of litter termination.

(iv) Toxic or other effects on reproduction, offspring, or postnatal growth.

(v) Developmental milestone data (mean age of vaginal opening and preputial separation, and mean anogenital distance, when measured).

(vi) Number of P and F1 females cycling normally and mean estrous cycle length.

(vii) Day (week) of observation of each abnormal sign and its subsequent course.

(viii) Body weight and body weight change data by sex for P, F1, and F2 animals.

(ix) Food (and water, if applicable) consumption, food efficiency (body weight gain per gram of food consumed), and test material consumption for P and F1 animals, except for the period of cohabitation.

(x) Total cauda epididymal sperm number, homogenization-resistant testis spermatid number, number and percent of progressively motile sperm, number and percent of morphologically normal sperm, and number and percent of sperm with each identified anomaly.

(xi) Stage of the estrous cycle at the time of termination for P and F1 parental females.

(xii) Necropsy findings.

(xiii) Implantation data and postimplantation loss calculations for P and F1 parental females.

(xiv) Absolute and adjusted organ weight data.

(xv) Detailed description of all histopathological findings.

(xvi) Adequate statistical treatment of results.

(xvii) A copy of the study protocol and any amendments should be included.

(g) *References.* For additional background information on this test guideline, the following references should be consulted. These references are available for inspection at the TSCA Nonconfidential Information Center, Rm. NE-B607, Environmental Protection Agency, 401 M St., SW., Washington, DC, 12 noon to 4 p.m., Monday through Friday, except legal holidays.

(1) Gray, L.E. *et al.* A dose-response analysis of methoxychlor-induced alterations of reproductive development and function in the rat. *Fundamental and Applied Toxicology*. 12:92-108 (1989).

(2) Heindel, J.J. *et al.* Ed. Hirshfield, A.N. Histological assessment of ovarian follicle number in mice as a screen of ovarian toxicity. *Growth Factors and the Ovary* (Plenum, NY, 1989) pp. 421-426.

(3) Korenbrot, C.C. *et al.* Preputial separation as an external sign of pubertal development in the male rat. *Biology of Reproduction*. 17:298-303 (1977).

(4) Linder, R.E. *et al.* Endpoints of spermatotoxicity in the rat after short duration exposures to fourteen reproductive toxicants. *Reproductive Toxicology*. 6:491-505 (1992).

(5) Manson, J.M. and Kang, Y.J. Ed. Hayes, A.W. Test methods for assessing female reproductive and developmental toxicology. *Principles and Methods of Toxicology* (Raven, NY, 1989).

(6) Organisation for Economic Co-operation and Development, No. 416: Two Generation Reproduction Toxicity Study, Guidelines for Testing of Chemicals. [C(83)44 (Final)] (1983).

(7) Pederson, T. and Peters, H. Proposal for classification of oocytes and follicles in the mouse ovary. *Journal of Reproduction and Fertility*. 17:555-557 (1988).

(8) Seed, J., Chapin, R.E. E.D. Clegg, L.A. Dostal, R.H. Foote, M.E. Hurtt, G.R. Klinefelter, S.L. Makris, S.D. Perreault, S. Schrader, D. Seyler, R. Sprando, K.A. Treinen, D.N.R. Veeramachaneni, and Wise, L.D. Methods for assessing sperm motility, morphology, and counts in the rat, rabbit, and dog: a consensus report. *Reproductive Toxicology*. 10(3):237-244 (1996).

(9) Smith, B.J. *et al.* Comparison of random and serial sections in assessment of ovarian toxicity. *Reproductive Toxicology*. 5:379–383 (1991).

(10) Thomas, J.A. Eds. M.O. Amdur, J. Doull, and C.D. Klaassen. Toxic responses of the reproductive system. *Casarett and Doull's Toxicology* (Pergamon, NY, 1991).

(11) Working, P.K. and Hurtt, M. Computerized videomicrographic analysis of rat sperm motility. *Journal of Andrology*. 8:330–337 (1987).

(12) Zenick, H. *et al.* Ed. Hayes, A.W. Assessment of male reproductive toxicity: a risk assessment approach. *Principles and Methods of Toxicology* (Raven, NY, 1994).

§ 799.9420 TSCA carcinogenicity.

(a) *Scope.* This section is intended to meet the testing requirements under section 4 of TSCA. The objective of a long-term carcinogenicity study is to observe test animals for a major portion of their life span for development of neoplastic lesions during or after exposure to various doses of a test substance by an appropriate route of administration.

(b) *Source.* The source material used in developing this TSCA test guideline is the OPPTS harmonized test guideline 870.4200 (June 1996 Public Draft). This source is available at the address in paragraph (g) of this section.

(c) *Definitions.* The following definitions apply to this section.

Carcinogenicity is the development of neoplastic lesions as a result of the repeated daily exposure of experimental animals to a chemical by the oral, dermal, or inhalation routes of exposure.

Cumulative toxicity is the adverse effects of repeated dose occurring as a result of prolonged action on, or increased concentration of, the administered test substance or its metabolites in susceptible tissues.

Dose in a carcinogenicity study is the amount of test substance administered via the oral, dermal or inhalation routes for a period of up to 24 months. Dose is expressed as weight of the test substance (grams, milligrams) per unit body weight of test animal (milligram per kilogram), or as weight of the test substance in parts per million (ppm) in food or drinking water. When exposed via inhalation, dose is expressed as weight of the test substance per unit volume of air (milligrams per liter) or as parts per million.

Target organ is any organ of a test animal showing evidence of an effect induced by a test substance.

(d) *Test procedures*—(1) *Animal selection*—(i) *Species and strain.* Testing shall be performed on two mammalian species. Rats and mice are the species of choice because of their relatively short life spans, limited cost of maintenance, widespread use in pharmacological and toxicological studies, susceptibility to tumor induction, and the availability of inbred or sufficiently characterized strains. Commonly used laboratory strains shall be used. If other mammalian species are used, the tester shall provide justification/reasoning for their selection.

(ii) *Age/weight.* (A) Testing shall be started with young healthy animals as soon as possible after weaning and acclimatization.

(B) Dosing should generally begin no later than 8 weeks of age.

(C) At commencement of the study, the weight variation of animals used shall not exceed $\pm 20\%$ of the mean weight for each sex.

(D) Studies using prenatal or neonatal animals may be recommended under special conditions.

(iii) *Sex.* (A) Equal numbers of animals of each sex shall be used at each dose level.

(B) Females shall be nulliparous and nonpregnant.

(iv) *Numbers.* (A) At least 100 rodents (50 males and 50 females) shall be used at each dose level and concurrent control group.

(B) If interim sacrifices are planned, the number shall be increased by the number of animals scheduled to be sacrificed during the course of the study.

(C) For a meaningful and valid statistical evaluation of long term exposure and for a valid interpretation of negative results, the number of animals in any group should not fall below 50% at 15 months in mice and 18 months in rats. Survival in any group should not fall below 25% at 18 months in mice and 24 months in rats.

(D) The use of adequate randomization procedures for the proper allocation of animals to test and control groups is required to avoid bias.

(E) Each animal shall be assigned a unique identification number. Dead animals, their preserved organs and tissues, and microscopic slides shall be identified by reference to the unique numbers assigned.

(v) *Husbandry.* (A) Animals may be group-caged by sex, but the number of animals per cage must not interfere with clear observation of each animal. The biological properties of the test substance or toxic effects (e.g., morbidity, excitability) may indicate a

need for individual caging. Animals should be housed individually in dermal studies and during exposure in inhalation studies.

(B) The temperature of the experimental animal rooms should be at 22 ± 3 °C.

(C) The relative humidity of the experimental animal rooms should be 30 to 70%.

(D) Where lighting is artificial, the sequence should be 12 h light/12 h dark.

(E) Control and test animals should be fed from the same batch and lot. The feed should be analyzed to assure uniform distribution and adequacy of nutritional requirements of the species tested and for impurities that might influence the outcome of the test. Animals should be fed and watered ad libitum with food replaced at least weekly.

(F) The study should not be initiated until animals have been allowed a period of acclimatization/quarantine to environmental conditions, nor should animals from outside sources be placed on test without an adequate period of quarantine.

(2) *Control and test substances.* (i) Where necessary, the test substance is dissolved or suspended in a suitable vehicle. If a vehicle or diluent is needed, it should not elicit toxic effects itself. It is recommended that wherever possible the use of an aqueous solution be considered first, followed by consideration of solution in oil, and finally solution in other vehicles.

(ii) One lot of the test substance should be used, if possible, throughout the duration of the study, and the research sample should be stored under conditions that maintain its purity and stability. Prior to the initiation of the study, there should be a characterization of the test substance, including the purity of the test compound, and, if possible, the name and quantities of contaminants and impurities.

(iii) If the test or control substance is to be incorporated into feed or another vehicle, the period during which the test substance is stable in such a mixture should be determined prior to the initiation of the study. Its homogeneity and concentration should be determined prior to the initiation of the study and periodically during the study. Statistically randomized samples of the mixture should be analyzed to ensure that proper mixing, formulation, and storage procedures are being followed, and that the appropriate concentration of the test or control substance is contained in the mixture.

(3) *Control groups.* A concurrent control group (50 males and 50 females) is required. This group shall be

untreated or if a vehicle is used in administering the test substance, a vehicle control group. If the toxic properties of the vehicle are not known, both untreated and vehicle control groups are required.

(4) *Dose levels and dose selection.* (i) For risk assessment purposes, at least three dose levels shall be used, in addition to the concurrent control group. Dose levels should be spaced to produce a gradation of effects. A rationale for the doses selected must be provided.

(ii) The highest dose level should elicit signs of toxicity without substantially altering the normal life span due to effects other than tumors. The highest dose should be determined based on the findings from a 90-day study to ensure that the dose used is adequate to assess the carcinogenic potential of the test substance. Thus, the selection of the highest dose to be tested is dependent upon changes observed in several toxicological parameters in subchronic studies. The highest dose tested need not exceed 1,000 mg/kg/day.

(iii) The intermediate-dose level should be spaced to produce a gradation of toxic effects.

(iv) The lowest dose level should produce no evidence of toxicity.

(v) For skin carcinogenicity studies, when toxicity to the skin is a determining factor, the highest dose selected should not destroy the functional integrity of the skin, the intermediate dose should be a minimally irritating dose, and the low dose should be the highest nonirritating dose.

(vi) The criteria for selecting the dose levels for skin carcinogenicity studies, based on gross and histopathologic dermal lesions, are as follows:

(A) Gross criteria for reaching the high dose:

- (1) Erythema (moderate).
- (2) Scaling.
- (3) Edema (mild).
- (4) Alopecia.
- (5) Thickening.

(B) Histologic criteria for reaching the high dose:

- (1) Epidermal hyperplasia.
- (2) Epidermal hyperkeratosis.
- (3) Epidermal parakeratosis.
- (4) Adnexal atrophy/hyperplasia.
- (5) Fibrosis.
- (6) Spongiosis (minimal-mild).
- (7) Epidermal edema (minimal-mild).
- (8) Dermal edema (minimal-moderate).

- (9) Inflammation (moderate).

(C) Gross criteria for exceeding the high dose:

- (1) Ulcers, fissures.
- (2) Exudate/crust (eschar).

(3) nonviable (dead) tissues.

(4) Anything leading to destruction of the functional integrity of the epidermis (e.g., caking, fissuring, open sores, eschar).

(D) Histologic criteria for exceeding the high dose:

(1) Crust (interfollicular and follicular).

(2) Microulcer.

(3) Degeneration/necrosis (mild to moderate).

(4) Epidermal edema (moderate to marked).

(5) Dermal edema (marked).

(6) Inflammation (marked).

(5) *Administration of the test substance.* The three main routes of administration are oral, dermal, and inhalation. The choice of the route of administration depends upon the physical and chemical characteristics of the test substance and the form typifying exposure in humans.

(i) *Oral studies.* If the test substance is administered by gavage, the animals are dosed with the test substance on a 7-day per week basis for a period of at least 18 months for mice and hamsters and 24 months for rats. However, based primarily on practical considerations, dosing by gavage or via a capsule on a 5-day per week basis is acceptable. If the test substance is administered in the drinking water or mixed in the diet, then exposure should be on a 7-day per week basis.

(ii) *Dermal studies.* (A) The animals should be treated with the test substance for at least 6 h/day on a 7-day per week basis for a period of at least 18 months for mice and hamsters and 24 months for rats. However, based primarily on practical considerations, application on a 5-day per week basis is acceptable. Dosing should be conducted at approximately the same time each day.

(B) Fur should be clipped weekly from the dorsal area of the trunk of the test animals. Care should be taken to avoid abrading the skin which could alter its permeability. A minimum of 24 hrs should be allowed for the skin to recover before the next dosing of the animal.

(C) The test substance shall be applied uniformly over a shaved area which is approximately 10% of the total body surface area. In order to dose approximately 10% of the body surface, the area starting at the scapulae (shoulders) to the wing of the ileum (hipbone) and half way down the flank on each side of the animal should be shaved. The volume of application should be kept constant and should not exceed 100 μ L for the mouse and 300 μ L for the rat; different concentrations of

the test solution should be prepared for different dose levels. With highly toxic substances, the surface area covered may be less, but as much of the area as possible should be covered with as thin and uniform a film as practical. The test material is not removed after application.

(D) During the exposure period, the application site should not be covered when mice or hamsters are the species of choice. For rats, the test substance may be held in contact with the skin with a porous gauze dressing and nonirritating tape if necessary. The test site should be further covered in a suitable manner to retain the gauze dressing and test substance and ensure that the animals cannot ingest the test substance.

(iii) *Inhalation studies.* (A) The animals should be exposed to the test substance for 6 h/day on a 7-day per week basis, for a period of at least 18 months in mice and 24 months in rats. However, based primarily on practical considerations, exposure for 6 h/day on a 5-day per week basis is acceptable.

(B) The animals shall be tested in dynamic inhalation equipment designed to sustain a minimum air flow of 10 air changes per hr, an adequate oxygen content of at least 19%, and uniform conditions throughout the exposure chamber. Maintenance of slight negative pressure inside the chamber will prevent leakage of the test substance into surrounding areas.

(C) The selection of a dynamic inhalation chamber should be appropriate for the test substance and test system. Where a whole body chamber is used to expose animals to an aerosol, individual housing must be used to minimize crowding of the test animals and maximize their exposure to the test substance. To ensure stability of a chamber atmosphere, the total volume occupied by the test animals shall not exceed 5% of the volume of the test chamber. It is recommended, but not required, that nose-only or head-only exposure be used for aerosol studies in order to minimize oral exposures due to animals licking compound off their fur. Heat stress to the animals should be minimized.

(D) The temperature at which the test is performed should be maintained at 22 ± 2 °C. The relative humidity should be maintained between 40 to 60%, but in certain instances (e.g., tests of aerosols, use of water vehicle) this may not be practicable.

(E) The rate of air flow shall be monitored continuously but recorded at least three times during exposure.

(F) Temperature and humidity shall be monitored continuously but should be recorded at least every 30 minutes.

(G) The actual concentrations of the test substance shall be measured in the breathing zone. During the exposure period, the actual concentrations of the test substance should be held as constant as practicable, monitored continuously or intermittently depending on the method of analysis. Chamber concentrations may be measured using gravimetric or analytical methods as appropriate. If trial run measurements are reasonably consistent ($\pm 10\%$ for liquid aerosol, gas, or dry aerosol), the two measurements should be sufficient. If measurements are not consistent, then three to four measurements should be taken.

(H) During the development of the generating system, particle size analysis shall be performed to establish the stability of aerosol concentrations with respect to particle size. Measurement of aerodynamic particle size in the animals's breathing zone should be measured during a trial run. If median aerodynamic diameter (MMAD) values for each exposure level are within 10% of each other, then two measurements during the exposures should be sufficient. If pretest measurements are not within 10% of each other, three to four measurements should be taken. The MMAD particle size range should be between 1–3 μm . The particle size of hygroscopic materials should be small enough to allow pulmonary deposition once the particles swell in the moist environment of the respiratory tract.

(I) Feed shall be withheld during exposure. Water may also be withheld during exposure.

(6) *Observation period.* It is necessary that the duration of the carcinogenicity study comprise the majority of the normal life span of the strain of animals used. This time period shall not be less than 24 months for rats and 18 months for mice, and ordinarily not longer than 30 months for rats and 24 months for mice. For longer time periods, and where any other species are used, consultation with the Agency in regard to the duration of the study is advised.

(7) *Observation of animals.* (i) Observations shall be made at least once each day for morbidity and mortality. Appropriate actions should be taken to minimize loss of animals from the study (e.g., necropsy or refrigeration of those animals found dead and isolation or sacrifice of weak or moribund animals).

(ii) A careful clinical examination shall be made at least once weekly. Observations should be detailed and carefully recorded, preferably using explicitly defined scales. Observations

should include, but not be limited to, evaluation of skin and fur, eyes and mucous membranes, respiratory and circulatory effects, autonomic effects such as salivation, central nervous system effects, including tremors and convulsions, changes in the level of activity, gait and posture, reactivity to handling or sensory stimuli, altered strength and stereotypes or bizarre behavior (e.g., self-mutilation, walking backwards).

(iii) Body weights shall be recorded individually for all animals; once a week during the first 13 weeks of the study and at least once every 4 weeks, thereafter, unless signs of clinical toxicity suggest more frequent weighing to facilitate monitoring of health status.

(iv) When the test substance is administered in the feed or drinking water, measurements of feed or water consumption, respectively, should be determined weekly during the first 13 weeks of the study and then at approximately monthly intervals unless health status or body weight changes dictate otherwise.

(v) Moribund animals shall be removed and sacrificed when noticed and the time of death should be recorded as precisely as possible. At the end of the study period, all survivors shall be sacrificed.

(8) *Clinical pathology.* At 12 months, 18 months, and at terminal sacrifice, a blood smear shall be obtained from all animals. A differential blood count should be performed on blood smears from those animals in the highest dosage group and the controls from the terminal sacrifice. If these data, or data from the pathological examination indicate a need, then the 12- and 18-month blood smears should also be examined. Differential blood counts should be performed for the next lower groups if there is a major discrepancy between the highest group and the controls. If clinical observations suggest a deterioration in health of the animals during the study, a differential blood count of the affected animals shall be performed.

(9) *Gross necropsy.* (i) A complete gross examination shall be performed on all animals, including those that died during the experiment or were killed in a moribund condition.

(ii) The liver, lungs, kidneys, brain, and gonads should be trimmed and weighed wet as soon as possible after dissection to avoid drying. The organs should be weighed from interim sacrifice animals as well as from at least 10 animals per sex per group at terminal sacrifice.

(iii) The following organs and tissues, or representative samples thereof, shall

be preserved in a suitable medium for possible future histopathological examination.

(A) Digestive system.

- (1) Salivary glands.
- (2) Esophagus.
- (3) Stomach.
- (4) Duodenum.
- (5) Jejunum.
- (6) Ileum.
- (7) Cecum.
- (8) Colon.
- (9) Rectum.
- (10) Liver.
- (11) Pancreas.
- (12) Gallbladder (mice).
- (13) Bile duct (rat).

(B) Nervous system.

- (1) Brain (multiple sections).
- (2) Pituitary.
- (3) Peripheral nerves.
- (4) Spinal cord (three levels).
- (5) Eyes (retina, optic nerve).

(C) Glandular system.

- (1) Adrenals.
 - (2) Parathyroids.
 - (3) Thyroids.
- (D) Respiratory system.
- (1) Trachea.
 - (2) Lung.
 - (3) Pharynx.
 - (4) Larynx.
 - (5) Nose (inhalation studies only).

(E) Cardiovascular/hematopoietic system.

- (1) Aorta (thoracic).
- (2) Heart.
- (3) Bone marrow.
- (4) Lymph nodes.
- (5) Spleen.
- (6) Thymus.
- (F) Urogenital system.
- (1) Kidneys.
- (2) Urinary bladder.
- (3) Prostate.
- (4) Testes/epididymides.
- (5) Seminal vesicles.
- (6) Uterus.
- (7) Ovaries.
- (G) Other.

- (1) Lacrimal gland.
- (2) Mammary gland.
- (3) Skin.
- (4) Skeletal muscle.
- (5) All gross lesions and masses.
- (6) Sternum and/or femur.

(iv) In inhalation studies, the entire respiratory tract, including nose, pharynx, larynx, and paranasal sinuses should be examined and preserved. In dermal studies, skin from treated and adjacent control skin sites should be examined and preserved.

(v) Inflation of lungs and urinary bladder with a fixative is the optimal method for preservation of these tissues. The proper inflation and fixation of the lungs in inhalation studies is essential for appropriate and valid histopathological examination.

(vi) Information from clinical pathology, and other in-life data should be considered before microscopic examination, since they may provide significant guidance to the pathologist.

(10) *Histopathology.* (i) The following histopathology shall be performed:

(A) Full histopathology on the organs and tissues under paragraph (d)(9) (iii) of this section of all animals in the control and high dose groups and all animals that died or were killed during the study.

(B) All gross lesions in all animals.

(C) Target organs in all animals.

(D) Lungs, liver, and kidneys of all animals. Special attention to examination of the lungs of rodents should be made for evidence of infection since this provides an assessment of the state of health of the animals.

(ii) If the results show substantial alteration of the animal's normal life span, the induction of effects that might affect a neoplastic response, or other effects that might compromise the significance of the data, the next lower dose levels shall be examined as described under paragraph (d)(11)(i) of this section.

(iii) An attempt should be made to correlate gross observations with microscopic findings.

(iv) Tissues and organs designated for microscopic examination should be fixed in 10% buffered formalin or a recognized suitable fixative as soon as necropsy is performed and no less than 48 hrs prior to trimming. Tissues should be trimmed to a maximum thickness of 0.4 cm for processing.

(e) *Data and reporting*—(1) *Treatment of results.* (i) Data shall be summarized in tabular form, showing for each test group the number of animals at the start of the test, the number of animals showing lesions, the types of lesions, and the percentage of animals displaying each type of lesion.

(ii) All observed results (quantitative and qualitative) shall be evaluated by an appropriate statistical method. Any generally accepted statistical methods may be used; the statistical methods including significance criteria shall be selected during the design of the study.

(2) *Evaluation of study results.* (i) The findings of a carcinogenicity study should be evaluated in conjunction with the findings of previous studies and considered in terms of the toxic effects, the necropsy and histopathological findings. The evaluation shall include the relationship between the dose of the test substance and the presence, incidence, and severity of abnormalities (including behavioral and clinical abnormalities), gross lesions, identified

target organs, body weight changes, effects on mortality, and any other general or specific toxic effects.

(ii) In any study which demonstrates an absence of toxic effects, further investigation to establish absorption and bioavailability of the test substance should be considered.

(iii) In order for a negative test to be acceptable, it must meet the following criteria: No more than 10% of any group is lost due to autolysis, cannibalism, or management problems; and survival in each group is no less than 50% at 15 months for mice and 18 months for rats. Survival should not fall below 25% at 18 months for mice and 24 months for rats.

(iv) The use of historical control data from an appropriate time period from the same testing laboratory (i.e., the incidence of tumors and other suspect lesions normally occurring under the same laboratory conditions and in the same strain of animals employed in the test) is helpful for assessing the significance of changes observed in the current study.

(3) *Test report.* (i) In addition to the reporting requirements as specified under 40 CFR part 792, subpart J, the following specific information shall be reported. Both individual and summary data should be presented.

(A) Test substance characterization should include:

(1) Chemical identification.

(2) Lot or batch number.

(3) Physical properties.

(4) Purity/impurities.

(5) Identification and composition of any vehicle used.

(B) Test system should contain data on:

(1) Species and strain of animals used and rationale for selection if other than that recommended.

(2) Age including body weight data and sex

(3) Test environment including cage conditions, ambient temperature, humidity, and light/dark periods.

(C) Test procedure should include the following data:

(1) Method of randomization used.

(2) Full description of experimental design and procedure.

(3) Dose regimen including levels, methods, and volume.

(4) *Test results*—(i) *Group animal data.* Tabulation of toxic response data by species, strain, sex, and exposure level for:

(A) Number of animals exposed.

(B) Number of animals showing signs of toxicity.

(C) Number of animals dying.

(ii) *Individual animal data.* Data should be presented as summary (group mean) as well as for individual animals.

(A) Time of death during the study or whether animals survived to termination.

(B) Time of observation of each abnormal sign and its subsequent course.

(C) Body weight data.

(D) Feed and water consumption data, when collected.

(E) Results of clinical pathology and immunotoxicity screen when performed.

(F) Necropsy findings including absolute/relative organ weight data.

(G) Detailed description of all histopathological findings.

(H) Statistical treatment of results where appropriate.

(I) Historical control data.

(iii) *Inhalation studies.* In addition, for inhalation studies the following shall be reported:

(A) *Test conditions.* The following exposure conditions shall be reported.

(1) Description of exposure apparatus including design, type, dimensions, source of air, system for generating particulate and aerosols, method of conditioning air, treatment of exhaust air and the method of housing the animals in a test chamber.

(2) The equipment for measuring temperature, humidity, and particulate aerosol concentrations and size should be described.

(B) *Exposure data.* These shall be tabulated and presented with mean values and a measure of variability (e.g. standard deviation) and should include:

(1) Airflow rates through the inhalation equipment.

(2) Temperature and humidity of air.

(3) Actual (analytical or gravimetric) concentration in the breathing zone.

(4) Nominal concentration (total amount of test substance fed into the inhalation equipment divided by volume of air).

(5) Particle size distribution, calculated MMAD and geometric standard deviation (GSD).

(6) Explanation as to why the desired chamber concentration and/or particle size could not be achieved (if applicable) and the efforts taken to comply with this aspect of the sections.

(f) *Quality assurance.* A system shall be developed and maintained to assure and document adequate performance of laboratory staff and equipment. The study shall be conducted in compliance with 40 CFR Part 792—Good Laboratory Practice Standards.

(g) *References.* For additional background information on this test guideline, the following references should be consulted. These references are available for inspection at the TSCA Nonconfidential Information Center,

Rm. NE-B607, Environmental Protection Agency, 401 M St., SW., Washington, DC, 12 noon to 4 p.m., Monday through Friday, except legal holidays.

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(4) Organisation for Economic Co-operation and Development. Guidelines for Testing of Chemicals, Section 4—Health Effects, Part 451 Carcinogenicity Studies (Paris, 1981).

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§ 799.9510 TSCA bacterial reverse mutation test.

(a) *Scope.* This section is intended to meet the testing requirements under section 4 of TSCA.

(1) The bacterial reverse mutation test uses amino-acid requiring strains of *Salmonella typhimurium* and *Escherichia coli* to detect point mutations, which involve substitution, addition or deletion of one or a few DNA base pairs. The principle of this bacterial reverse mutation test is that it detects mutations which revert mutations present in the test strains and restore the functional capability of the bacteria to synthesize an essential amino acid. The revertant bacteria are detected by their ability to grow in the absence of the amino acid required by the parent test strain.

(2) Point mutations are the cause of many human genetic diseases and there is substantial evidence that point mutations in oncogenes and tumor suppressor genes of somatic cells are

involved in tumor formation in humans and experimental animals. The bacterial reverse mutation test is rapid, inexpensive and relatively easy to perform. Many of the test strains have several features that make them more sensitive for the detection of mutations, including responsive DNA sequences at the reversion sites, increased cell permeability to large molecules and elimination of DNA repair systems or enhancement of error-prone DNA repair processes. The specificity of the test strains can provide some useful information on the types of mutations that are induced by genotoxic agents. A very large data base of results for a wide variety of structures is available for bacterial reverse mutation tests and well-established methodologies have been developed for testing chemicals with different physico-chemical properties, including volatile compounds.

(b) *Source.* The source material used in developing this TSCA test guideline are the OECD replacement guidelines for 471 and 472 (February 1997). This source is available at the address in paragraph (g) of this section.

(c) *Definitions.* The following definitions apply to this section:

A *reverse mutation test* in either *Salmonella typhimurium* or *Escherichia coli* detects mutation in an amino-acid requiring strain (histidine or tryptophan, respectively) to produce a strain independent of an outside supply of amino-acid.

Base pair substitution mutagens are agents that cause a base change in DNA. In a reversion test this change may occur at the site of the original mutation, or at a second site in the bacterial genome.

Frameshift mutagens are agents that cause the addition or deletion of one or more base pairs in the DNA, thus changing the reading frame in the RNA

(d) *Initial considerations.* (1) The bacterial reverse mutation test utilizes prokaryotic cells, which differ from mammalian cells in such factors as uptake, metabolism, chromosome structure and DNA repair processes. Tests conducted *in vitro* generally require the use of an exogenous source of metabolic activation. *In vitro* metabolic activation systems cannot mimic entirely the mammalian *in vivo* conditions. The test therefore does not provide direct information on the mutagenic and carcinogenic potency of a substance in mammals.

(2) The bacterial reverse mutation test is commonly employed as an initial screen for genotoxic activity and, in particular, for point mutation-inducing activity. An extensive data base has

demonstrated that many chemicals that are positive in this test also exhibit mutagenic activity in other tests. There are examples of mutagenic agents which are not detected by this test; reasons for these shortcomings can be ascribed to the specific nature of the endpoint detected, differences in metabolic activation, or differences in bioavailability. On the other hand, factors which enhance the sensitivity of the bacterial reverse mutation test can lead to an overestimation of mutagenic activity.

(3) The bacterial reverse mutation test may not be appropriate for the evaluation of certain classes of chemicals, for example highly bactericidal compounds (e.g. certain antibiotics) and those which are thought (or known) to interfere specifically with the mammalian cell replication system (e.g. some topoisomerase inhibitors and some nucleoside analogues). In such cases, mammalian mutation tests may be more appropriate.

(4) Although many compounds that are positive in this test are mammalian carcinogens, the correlation is not absolute. It is dependent on chemical class and there are carcinogens that are not detected by this test because they act through other, non-genotoxic mechanisms or mechanisms absent in bacterial cells.

(e) *Test method*—(1) *Principle.* (i) Suspensions of bacterial cells are exposed to the test substance in the presence and in the absence of an exogenous metabolic activation system. In the plate incorporation method, these suspensions are mixed with an overlay agar and plated immediately onto minimal medium. In the preincubation method, the treatment mixture is incubated and then mixed with an overlay agar before plating onto minimal medium. For both techniques, after 2 or 3 days of incubation, revertant colonies are counted and compared to the number of spontaneous revertant colonies on solvent control plates.

(ii) Several procedures for performing the bacterial reverse mutation test have been described. Among those commonly used are the plate incorporation method, the preincubation method, the fluctuation method, and the suspension method. Suggestions for modifications for the testing of gases or vapors are described in the reference in paragraph (g)(12) of this section.

(iii) The procedures described in this section pertain primarily to the plate incorporation and preincubation methods. Either of them is acceptable for conducting experiments both with and without metabolic activation. Some compounds may be detected more

efficiently using the preincubation method. These compounds belong to chemical classes that include short chain aliphatic nitrosamines, divalent metals, aldehydes, azo-dyes and diazo compounds, pyrrolizidine alkaloids, allyl compounds and nitro compounds. It is also recognized that certain classes of mutagens are not always detected using standard procedures such as the plate incorporation method or preincubation method. These should be regarded as "special cases" and it is strongly recommended that alternative procedures should be used for their detection. The following "special cases" could be identified (together with examples of procedures that could be used for their detection): azo-dyes and diazo compounds (alternative procedures are described in the references in paragraphs (g)(3), (g)(5), (g)(6), and (g)(13) of this section), gases and volatile chemicals (alternative procedures are described in the references in paragraphs (g)(12), (g)(14), (g)(15), and (g)(16) of this section), and glycosides (alternative procedures are described in the references in paragraphs (g)(17) and (g)(18) of this section). A deviation from the standard procedure needs to be scientifically justified.

(2) *Description*—(i) *Preparations*—(A) *Bacteria*. (1) Fresh cultures of bacteria should be grown up to the late exponential or early stationary phase of growth (approximately 10^9 cells per ml). Cultures in late stationary phase should not be used. The cultures used in the experiment shall contain a high titre of viable bacteria. The titre may be demonstrated either from historical control data on growth curves, or in each assay through the determination of viable cell numbers by a plating experiment.

(2) The culture temperature shall be 37°C.

(3) At least five strains of bacteria should be used. These should include four strains of *S. typhimurium* (TA1535; TA1537 or TA97a or TA97; TA98; and TA100) that have been shown to be reliable and reproducibly responsive between laboratories. These four *S. typhimurium* strains have GC base pairs at the primary reversion site and it is known that they may not detect certain oxidizing mutagens, cross-linking agents, and hydrazines. Such substances may be detected by *E. coli* WP2 strains or *S. typhimurium* TA102 (see paragraph (g)(19) of this section) which have an AT base pair at the primary reversion site. Therefore the recommended combination of strains is:

(i) *S. typhimurium* TA1535.

(ii) *S. typhimurium* TA1537 or TA97 or TA97a.

(iii) *S. typhimurium* TA98.

(iv) *S. typhimurium* TA100.

(v) *E. coli* WP2 *uvrA*, or *E. coli* WP2 *uvrA* (pKM101), or *S. typhimurium* TA102. In order to detect cross-linking mutagens it may be preferable to include TA102 or to add a DNA repair-proficient strain of *E. coli* [e.g. *E. coli* WP2 or *E. coli* WP2 (pKM101).]

(4) Established procedures for stock culture preparation, marker verification and storage should be used. The amino-acid requirement for growth should be demonstrated for each frozen stock culture preparation (histidine for *S. typhimurium* strains, and tryptophan for *E. coli* strains). Other phenotypic characteristics should be similarly checked, namely: the presence or absence of R-factor plasmids where appropriate [i.e. ampicillin resistance in strains TA98, TA100 and TA97a or TA97, WP2 *uvrA* and WP2 *uvrA* (pKM101), and ampicillin + tetracycline resistance in strain TA102]; the presence of characteristic mutations (i.e. *rfa* mutation in *S. typhimurium* through sensitivity to crystal violet, and *uvrA* mutation in *E. coli* or *uvrB* mutation in *S. typhimurium*, through sensitivity to ultra-violet light). The strains should also yield spontaneous revertant colony plate counts within the frequency ranges expected from the laboratory's historical control data and preferably within the range reported in the literature.

(B) *Medium*. An appropriate minimal agar (e.g. containing Vogel-Bonner minimal medium E and glucose) and an overlay agar containing histidine and biotin or tryptophan, to allow for a few cell divisions, shall be used. The procedures described in the references under paragraphs (g)(1), (g)(2), and (g)(9) of this section may be used for this analysis.

(C) *Metabolic activation*. Bacteria shall be exposed to the test substance both in the presence and absence of an appropriate metabolic activation system. The most commonly used system is a cofactor-supplemented post-mitochondrial fraction (S9) prepared from the livers of rodents treated with enzyme-inducing agents such as Aroclor 1254 (the system described in the references under paragraphs (g)(1) and (g)(2) of this section may be used) or a combination of phenobarbitone and β -naphthoflavone (the system described in the references under paragraphs (g)(18), (g)(20), and (g)(21) of this section may be used). The post-mitochondrial fraction is usually used at concentrations in the range from 5 to 30% v/v in the S9-mix. The choice and condition of a metabolic activation system may depend upon the class of

chemical being tested. In some cases it may be appropriate to utilize more than one concentration of post-mitochondrial fraction. For azo-dyes and diazo-compounds, using a reductive metabolic activation system may be more appropriate (the system described in the references under paragraphs (g)(6) and (g)(13) of this section may be used).

(D) *Test substance/preparation*. Solid test substances should be dissolved or suspended in appropriate solvents or vehicles and diluted if appropriate prior to treatment of the bacteria. Liquid test substances may be added directly to the test systems and/or diluted prior to treatment. Fresh preparations should be employed unless stability data demonstrate the acceptability of storage.

(ii) *Test conditions*—(A) *Solvent/vehicle*. The solvent/vehicle shall not be suspected of chemical reaction with the test substance and shall be compatible with the survival of the bacteria and the S9 activity (see paragraph (g)(22) of this section). If other than well-known solvent/vehicles are used, their inclusion should be supported by data indicating their compatibility. It is recommended that wherever possible, the use of an aqueous solvent/vehicle be considered first. When testing water-unstable substances, the organic solvents used should be free of water.

(B) *Exposure concentrations*. (1) Amongst the criteria to be taken into consideration when determining the highest amount of test substance to be used are cytotoxicity and solubility in the final treatment mixture. It may be useful to determine toxicity and insolubility in a preliminary experiment. Cytotoxicity may be detected by a reduction in the number of revertant colonies, a clearing or diminution of the background lawn, or the degree of survival of treated cultures. The cytotoxicity of a substance may be altered in the presence of metabolic activation systems. Insolubility should be assessed as precipitation in the final mixture under the actual test conditions and evident to the unaided eye. The recommended maximum test concentration for soluble non-cytotoxic substances is 5 mg/plate or 5 μ l/plate. For non-cytotoxic substances that are not soluble at 5mg/plate or 5 μ l/plate, one or more concentrations tested should be insoluble in the final treatment mixture. Test substances that are cytotoxic already below 5mg/plate or 5 μ l/plate should be tested up to a cytotoxic concentration. The precipitate should not interfere with the scoring.

(2) At least five different analyzable concentrations of the test substance shall be used with approximately half

log (i.e. $\sqrt{10}$) intervals between test points for an initial experiment. Smaller intervals may be appropriate when a concentration-response is being investigated.

(3) Testing above the concentration of 5 mg/plate or 5 μ l/plate may be considered when evaluating substances containing substantial amounts of potentially mutagenic impurities.

(C) *Controls.* (1) Concurrent strain-specific positive and negative (solvent or vehicle) controls, both with and without metabolic activation, shall be included in each assay. Positive control concentrations that demonstrate the effective performance of each assay should be selected.

(2)(i) For assays employing a metabolic activation system, the

positive control reference substance(s) should be selected on the basis of the type of bacteria strains used. The following chemicals are examples of suitable positive controls for assays with metabolic activation:

Chemical	CAS No.
9,10-Dimethylanthracene	[CAS no. 781-43-1]
7,12-Dimethylbenzanthracene	[CAS no. 57-97-6]
Congo Red (for the reductive metabolic activation method)	[CAS no. 573-58-0]
Benzo(a)pyrene	[CAS no. 50-32-8]
Cyclophosphamide (monohydrate)	[CAS no. 50-18-0]
	[CAS no. 6055-19-2]
2-Aminoanthracene	[CAS no. 613-13-8]

(ii) 2-Aminoanthracene should not be used as the sole indicator of the efficacy of the S9-mix. If 2-aminoanthracene is used, each batch of S9 should also be characterized with a mutagen that

requires metabolic activation by microsomal enzymes, e.g., benzo(a)pyrene, dimethylbenzanthracene.

(3) For assays performed without metabolic activation system, examples of strain-specific positive controls are:

Chemical	CAS No.	Strain
(a) Sodium azide	[CAS no. 26628-22-8]	TA1535 and TA100
(b) 2-Nitrofluorene	[CAS no. 607-57-8]	TA 98
(c) 9-Aminoacridine or ICR 191	[CAS no. 90-45-9] or	TA1537, TA97 and TA97a
	[CAS no. 17070-45-0]	
(d) Cumene hydroperoxide	[CAS no. 80-15-9]	TA102
(e) Mitomycin C	[CAS no. 50-07-7]	WP2 <i>uvrA</i> and TA102
(f) N-Ethyl-N-nitro-N-nitrosoguanidine or	[CAS no. 70-25-7] or	WP2, WP2 <i>uvrA</i> and WP2 <i>uvrA</i> (pKM101)
4-nitroquinoline 1-oxide	[CAS no. 56-57-5]	
(g) Furfuryluramide (AF-2)	[CAS no. 3688-53-7]	Plasmid-containing strains

(4) Other appropriate positive control reference substances may be used. The use of chemical class-related positive control chemicals may be considered, when available.

(5) Negative controls, consisting of solvent or vehicle alone, without test substance, and otherwise treated in the same way as the treatment groups, shall be included. In addition, untreated controls should also be used unless there are historical control data demonstrating that no deleterious or mutagenic effects are induced by the chosen solvent.

(3) *Procedure—(i) Treatment with test substance.* (A) For the plate incorporation method, without metabolic activation, usually 0.05 ml or 0.1 ml of the test solutions, 0.1 ml of fresh bacterial culture (containing approximately 10^8 viable cells) and 0.5 ml of sterile buffer are mixed with 2.0 ml of overlay agar. For the assay with metabolic activation, usually 0.5 ml of

metabolic activation mixture containing an adequate amount of post-mitochondrial fraction (in the range from 5 to 30% v/v in the metabolic activation mixture) are mixed with the overlay agar (2.0 ml), together with the bacteria and test substance/test solution. The contents of each tube are mixed and poured over the surface of a minimal agar plate. The overlay agar is allowed to solidify before incubation.

(B) For the preincubation method the test substance/test solution is preincubated with the test strain (containing approximately 10^8 viable cells) and sterile buffer or the metabolic activation system (0.5 ml) usually for 20 min. or more at 30–37 °C prior to mixing with the overlay agar and pouring onto the surface of a minimal agar plate. Usually, 0.05 or 0.1 ml of test substance/test solution, 0.1 ml of bacteria, and 0.5 ml of S9-mix or sterile buffer, are mixed with 2.0 ml of overlay agar. Tubes

should be aerated during pre-incubation by using a shaker.

(C) For an adequate estimate of variation, triplicate plating should be used at each dose level. The use of duplicate plating is acceptable when scientifically justified. The occasional loss of a plate does not necessarily invalidate the assay.

(D) Gaseous or volatile substances should be tested by appropriate methods, such as in sealed vessels (methods described in the references under paragraphs (g)(12), (g)(14), (g)(15), and (g)(16) of this section may be used).

(ii) *Incubation.* All plates in a given assay shall be incubated at 37 °C for 48–72 hrs. After the incubation period, the number of revertant colonies per plate is counted.

(f) *Data and reporting—(1) Treatment of results.* (i) Data shall be presented as the number of revertant colonies per plate. The number of revertant colonies on both negative (solvent control, and

untreated control if used) and positive control plates shall also be given.

(ii) Individual plate counts, the mean number of revertant colonies per plate and the standard deviation shall be presented for the test substance and positive and negative (untreated and/or solvent) controls.

(iii) There is no requirement for verification of a clear positive response. Equivocal results shall be clarified by further testing preferably using a modification of experimental conditions. Negative results need to be confirmed on a case-by-case basis. In those cases where confirmation of negative results is not considered necessary, justification should be provided. Modification of study parameters to extend the range of conditions assessed should be considered in follow-up experiments. Study parameters that might be modified include the concentration spacing, the method of treatment (plate incorporation or liquid preincubation), and metabolic activation conditions.

(2) *Evaluation and interpretation of results.* (i) There are several criteria for determining a positive result, such as a concentration-related increase over the range tested and/or a reproducible increase at one or more concentrations in the number of revertant colonies per plate in at least one strain with or without metabolic activation system. Biological relevance of the results should be considered first. Statistical methods may be used as an aid in evaluating the test results. However, statistical significance should not be the only determining factor for a positive response.

(ii) A test substance for which the results do not meet the criteria described under paragraph (f)(2)(i) of this section is considered non-mutagenic in this test

(iii) Although most experiments will give clearly positive or negative results, in rare cases the data set will preclude making a definite judgement about the activity of the test substance. Results may remain equivocal or questionable regardless of the number of times the experiment is repeated.

(iv) Positive results from the bacterial reverse mutation test indicate that a substance induces point mutations by base substitutions or frameshifts in the genome of either *Salmonella typhimurium* and/or *Escherichia coli*. Negative results indicate that under the test conditions, the test substance is not mutagenic in the tested species.

(3) *Test report.* In addition to the reporting requirements as specified under 40 CFR part 792, subpart J, the following specific information shall be

reported. Both individual and summary data should be presented.

(i) Test substance:

(A) Identification data and CAS no., if known.

(B) Physical nature and purity.

(C) Physicochemical properties relevant to the conduct of the study.

(D) Stability of the test substance, if known.

(ii) Solvent/vehicle:

(A) Justification for choice of solvent/vehicle.

(B) Solubility and stability of the test substance in solvent/vehicle, if known.

(iii) Strains:

(A) Strains used.

(B) Number of cells per culture.

(C) Strain characteristics.

(iv) Test conditions:

(A) Amount of test substance per plate (mg/plate or ml/plate) with rationale for selection of dose and number of plates per concentration.

(B) Media used.

(C) Type and composition of metabolic activation system, including acceptability criteria.

(D) Treatment procedures.

(v) Results:

(A) Signs of toxicity.

(B) Signs of precipitation.

(C) Individual plate counts.

(D) The mean number of revertant colonies per plate and standard deviation.

(E) Dose-response relationship, where possible.

(F) Statistical analyses, if any.

(G) Concurrent negative (solvent/vehicle) and positive control data, with ranges, means and standard deviations.

(H) Historical negative (solvent/vehicle) and positive control data, with e.g. ranges, means and standard deviations.

(vi) Discussion of the results.

(vii) Conclusion.

(g) *References.* For additional background information on this test guideline, the following references should be consulted. These references are available for inspection at the TSCA Nonconfidential Information Center, Rm. NE-B607, Environmental Protection Agency, 401 M St., SW., Washington, DC, 12 noon to 4 p.m., Monday through Friday, except legal holidays.

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§ 799.9530 TSCA *in vitro* mammalian cell gene mutation test.

(a) *Scope*. This section is intended to meet the testing requirements under section 4 of TSCA. The *in vitro* mammalian cell gene mutation test can be used to detect gene mutations induced by chemical substances. Suitable cell lines include L5178Y mouse lymphoma cells, the CHO, AS52 and V79 lines of Chinese hamster cells, and TK6 human lymphoblastoid cells under paragraph (g)(1) of this section. In these cell lines the most commonly-used genetic endpoints measure mutation at thymidine kinase (TK) and hypoxanthine-guanine phosphoribosyl transferase (HPRT), and a transgene of xanthine-guanine phosphoribosyl transferase (XPRT). The TK, HPRT and XPRT mutation tests detect different spectra of genetic events. The autosomal location of TK and XPRT may allow the detection of genetic events (e.g. large deletions) not detected at the HPRT locus on X-chromosomes (For a discussion see the references in paragraphs (g)(2), (g)(3), (g)(4), (g)(5), and (g)(6) of this section).

(b) *Source*. The source material used in developing this TSCA test guideline is the OECD guideline 476 (February 1997). This source is available at the address in paragraph (g) of this section.

(c) *Definitions*. The following definitions apply to this section:

Base pair substitution mutagens are substances which cause substitution of one or several base pairs in the DNA.

Forward mutation is a gene mutation from the parental type to the mutant form which gives rise to an alteration or a loss of the enzymatic activity or the function of the encoded protein.

Frameshift mutagens are substances which cause the addition or deletion of single or multiple base pairs in the DNA molecule.

Mutant frequency is the number of mutant cells observed divided by the number of viable cells.

Phenotypic expression time is a period during which unaltered gene products are depleted from newly mutated cells.

Relative suspension growth is an increase in cell number over the expression period relative to the negative control.

Relative total growth is an increase in cell number over time compared to a control population of cells; calculated as the product of suspension growth relative to the negative control times cloning efficiency relative to negative control.

Survival is the cloning efficiency of the treated cells when plated at the end of the treatment period; survival is usually expressed in relation to the survival of the control cell population.

Viability is the cloning efficiency of the treated cells at the time of plating in selective conditions after the expression period.

(d) *Initial considerations*. (1) In the *in vitro* mammalian cell gene mutation test, cultures of established cell lines or cell strains can be used. The cells used are selected on the basis of growth ability in culture and stability of the spontaneous mutation frequency. Tests conducted *in vitro* generally require the use of an exogenous source of metabolic activation. This metabolic activation system cannot mimic entirely the mammalian *in vivo* conditions. Care should be taken to avoid conditions which would lead to results not reflecting intrinsic mutagenicity. Positive results which do not reflect intrinsic mutagenicity may arise from changes in pH, osmolality or high levels of cytotoxicity.

(2) This test is used to screen for possible mammalian mutagens and carcinogens. Many compounds that are positive in this test are mammalian carcinogens; however, there is not a perfect correlation between this test and carcinogenicity. Correlation is dependent on chemical class and there is increasing evidence that there are carcinogens that are not detected by this test because they appear to act through other, non-genotoxic mechanisms or mechanisms absent in bacterial cells.

(e) *Test method*—(1) *Principle*. (i) Cells deficient in thymidine kinase (TK) due to the mutation TK⁺/– ≤ TK[–]/– are resistant to the cytotoxic effects of the pyrimidine analogue trifluorothymidine (TFT). Thymidine kinase proficient cells are sensitive to TFT, which causes the inhibition of cellular metabolism and halts further cell division. Thus mutant cells are able to proliferate in the presence of TFT, whereas normal cells, which contain thymidine kinase, are not. Similarly, cells deficient in HPRT or XPRT are selected by resistance to 6-thioguanine (TG) or 8-azaguanine (AG). The properties of the test substance should be considered carefully if a base analogue or a compound related to the selective agent is tested in any of the mammalian cell gene mutation tests. For example, any suspected selective

toxicity by the test substance for mutant and non-mutant cells should be investigated. Thus, performance of the selection system/agent shall be confirmed when testing chemicals structurally related to the selective agent.

(ii) Cells in suspension or monolayer culture shall be exposed to the test substance, both with and without metabolic activation, for a suitable period of time and subcultured to determine cytotoxicity and to allow phenotypic expression prior to mutant selection. Cytotoxicity is usually determined by measuring the relative cloning efficiency (survival) or relative total growth of the cultures after the treatment period. The treated cultures shall be maintained in growth medium for a sufficient period of time, characteristic of each selected locus and cell type, to allow near-optimal phenotypic expression of induced mutations. Mutant frequency is determined by seeding known numbers of cells in medium containing the selective agent to detect mutant cells, and in medium without selective agent to determine the cloning efficiency (viability). After a suitable incubation time, colonies shall be counted. The mutant frequency is derived from the number of mutant colonies in selective medium and the number of colonies in non-selective medium.

(2) *Description*—(i) *Preparations*—(A) *Cells*. (1) A variety of cell types are available for use in this test including subclones of L5178Y, CHO, CHO-AS52, V79, or TK6 cells. Cell types used in this test should have a demonstrated sensitivity to chemical mutagens, a high cloning efficiency and a stable spontaneous mutant frequency. Cells should be checked for mycoplasma contamination and should not be used if contaminated.

(2) The test should be designed to have a predetermined sensitivity and power. The number of cells, cultures, and concentrations of test substance used should reflect these defined parameters. The parameters discussed in the reference under paragraph (g)(13) of this section may be used. The minimal number of viable cells surviving treatment and used at each stage in the test should be based on the spontaneous mutation frequency. A general guide is to use a cell number which is at least ten times the inverse of the spontaneous mutation frequency. However, it is recommended to utilize at least 10^6 cells. Adequate historical data on the cell system used should be available to indicate consistent performance of the test.

(B) *Media and culture conditions*.

Appropriate culture media and incubation conditions (culture vessels, temperature, CO₂ concentration and humidity) shall be used. Media should be chosen according to the selective systems and cell type used in the test. It is particularly important that culture conditions should be chosen that ensure optimal growth of cells during the expression period and colony forming ability of both mutant and non-mutant cells.

(C) *Preparation of cultures*. Cells are propagated from stock cultures, seeded in culture medium and incubated at 37°C. Prior to use in this test, cultures may need to be cleansed of pre-existing mutant cells.

(D) *Metabolic activation*. Cells shall be exposed to the test substance both in the presence and absence of an appropriate metabolic activation system. The most commonly used system is a co-factor-supplemented post-mitochondrial fraction (S9) prepared from the livers of rodents treated with enzyme-inducing agents such as Aroclor 1254 or a combination of phenobarbitone and β -naphthoflavone. The post-mitochondrial fraction is usually used at concentrations in the range from 1–10% v/v in the final test medium. The choice and condition of a metabolic activation system may depend upon the class of chemical being tested. In some cases it may be appropriate to utilize more than one concentration of post-mitochondrial fraction. A number of developments, including the construction of genetically engineered cell lines expressing specific activating enzymes, may provide the potential for endogenous activation. The choice of the cell lines used should be scientifically justified (e.g. by the relevance of the cytochrome P450 isoenzyme to the metabolism of the test substance).

(E) *Test substance/preparations*. Solid test substances should be dissolved or suspended in appropriate solvents or vehicles and diluted if appropriate prior to treatment of the cells. Liquid test substances may be added directly to the test systems and/or diluted prior to treatment. Fresh preparations should be employed unless stability data demonstrate the acceptability of storage.

(ii) *Test conditions*—(A) *Solvent/vehicle*. The solvent/vehicle shall not be suspected of chemical reaction with the test substance and shall be compatible with the survival of the cells and the S9 activity. If other than well-known solvent/vehicles are used, their inclusion should be supported by data indicating their compatibility. It is

recommended that wherever possible, the use of an aqueous solvent/vehicle be considered first. When testing water-unstable substances, the organic solvents used should be free of water. Water can be removed by adding a molecular sieve.

(B) *Exposure concentrations*. (1) Among the criteria to be considered when determining the highest concentration are cytotoxicity and solubility in the test system and changes in pH or osmolality.

(2) Cytotoxicity should be determined with and without metabolic activation in the main experiment using an appropriate indicator of cell integrity and growth, such as relative cloning efficiency (survival) or relative total growth. It may be useful to determine cytotoxicity and solubility in a preliminary experiment.

(3) At least four analyzable concentrations shall be used. Where there is cytotoxicity, these concentrations shall cover a range from the maximum to little or no toxicity; this will usually mean that the concentration levels should be separated by no more than a factor between 2 and $\sqrt{10}$. If the maximum concentration is based on cytotoxicity then it shall result in approximately 10–20% but not less than 10% relative survival (relative cloning efficiency) or relative total growth. For relatively non-cytotoxic compounds the maximum concentration should be 5 mg/ml, 5 μ l/ml, or 0.01 M, whichever is the lowest.

(4) Relatively insoluble substances should be tested up to or beyond their limit of solubility under culture conditions. Evidence of insolubility should be determined in the final treatment medium to which cells are exposed. It may be useful to assess solubility at the beginning and end of the treatment, as solubility can change during the course of exposure in the test system due to presence of cells, S9, serum etc. Insolubility can be detected by using the unaided eye. The precipitate should not interfere with the scoring.

(C) *Controls*. (1) Concurrent positive and negative (solvent or vehicle) controls both with and without metabolic activation shall be included in each experiment. When metabolic activation is used the positive control chemical shall be one that requires activation to give a mutagenic response.

(2) Examples of positive control substances include:

Metabolic Activation condition	Locus	Chemical	CAS No.
Absence of exogenous metabolic activation	HPRT	Ethylmethanesulfonate	[CAS no. 62-50-0]
	TK (small and large colonies).	Ethyl nitrosourea	[CAS no. 759-73-9]
		Methylmethanesulfonate	[CAS no. 66-27-3]
Presence of exogenous metabolic activation.	XPRT	Ethylmethanesulfonate	[CAS no. 62-50-0]
	HPRT	Ethyl nitrosourea	[CAS no. 759-73-9]
		3-Methylcholanthrene	[CAS no. 56-49-5]
		N-Nitrosodimethylamine	[CAS no. 62-75-9]
	TK (small and large colonies).	7,12-Dimethylbenzanthracene	[CAS no. 57-97-6]
		Cyclophosphamide (monohydrate)	[CAS no. 50-18-0]
		Benzo(a)pyrene	[CAS no. 6055-19-2]
		3-Methylcholanthrene	[CAS no. 50-32-8]
	XPRT	N-Nitrosodimethylamine (for high levels of S-9)	[CAS no. 62-75-9]
		Benzo(a)pyrene	[CAS no. 50-32-8]

(3) Other appropriate positive control reference substances may be used, e.g., if a laboratory has a historical data base on 5-Bromo 2'-deoxyuridine [CAS No. 59-14-3], this reference substance could be used as well. The use of chemical class-related positive control chemicals may be considered, when available.

(4) Negative controls, consisting of solvent or vehicle alone in the treatment medium, and treated in the same way as the treatment groups shall be included. In addition, untreated controls should also be used unless there are historical control data demonstrating that no deleterious or mutagenic effects are induced by the chosen solvent.

(3) *Procedure*—(i) *Treatment with test substance*. (A) Proliferating cells shall be exposed to the test substance both with and without metabolic activation. Exposure shall be for a suitable period of time (usually 3 to 6 hrs is effective). Exposure time may be extended over one or more cell cycles.

(B) Either duplicate or single treated cultures may be used at each concentration tested. When single cultures are used, the number of concentrations should be increased to ensure an adequate number of cultures for analysis (e.g. at least eight analyzable concentrations). Duplicate negative (solvent) control cultures should be used.

(C) Gaseous or volatile substances should be tested by appropriate methods, such as in sealed culture vessels. Methods described in the references under paragraphs (g)(20) and (g)(21) of this section may be used.

(ii) *Measurement of survival, viability, and mutant frequency*. (A) At the end of the exposure period, cells shall be washed and cultured to determine survival and to allow for expression of

the mutant phenotype. Measurement of cytotoxicity by determining the relative cloning efficiency (survival) or relative total growth of the cultures is usually initiated after the treatment period.

(B) Each locus has a defined minimum time requirement to allow near optimal phenotypic expression of newly induced mutants (HPRT and XPRT require at least 6–8 days, and TK at least 2 days). Cells are grown in medium with and without selective agent(s) for determination of numbers of mutants and cloning efficiency, respectively. The measurement of viability (used to calculate mutant frequency) is initiated at the end of the expression time by plating in non-selective medium.

(C) If the test substance is positive in the L5178Y TK⁺/– test, colony sizing should be performed on at least one of the test cultures (the highest positive concentration) and on the negative and positive controls. If the test substance is negative in the L5178Y TK⁺/– test, colony sizing should be performed on the negative and positive controls. In studies using TK6TK⁺/–, colony sizing may also be performed.

(f) *Data and reporting*—(1) *Treatment of results*. (i) Data shall include cytotoxicity and viability determination, colony counts and mutant frequencies for the treated and control cultures. In the case of a positive response in the L5178Y TK⁺/– test, colonies are scored using the criteria of small and large colonies on at least one concentration of the test substance (highest positive concentration) and on the negative and positive control. The molecular and cytogenetic nature of both large and small colony mutants has been explored in detail and is discussed in the references under paragraphs (g)(22) and

(g)(23) of this section. In the TK⁺/– test, colonies are scored using the criteria of normal growth (large) and slow growth (small) colonies (a scoring system similar to the one described in the reference under paragraph (g)(24) of this section may be used). Mutant cells that have suffered the most extensive genetic damage have prolonged doubling times and thus form small colonies. This damage typically ranges in scale from the losses of the entire gene to karyotypically visible chromosome aberrations. The induction of small colony mutants has been associated with chemicals that induce gross chromosome aberrations. Less seriously affected mutant cells grow at rates similar to the parental cells and form large colonies.

(ii) Survival (relative cloning efficiencies) or relative total growth shall be given. Mutant frequency shall be expressed as number of mutant cells per number of surviving cells.

(iii) Individual culture data shall be provided. Additionally, all data shall be summarized in tabular form.

(iv) There is no requirement for verification of a clear positive response. Equivocal results shall be clarified by further testing preferably using a modification of experimental conditions. Negative results need to be confirmed on a case-by-case basis. In those cases where confirmation of negative results is not considered necessary, justification should be provided. Modification of study parameters to extend the range of conditions assessed should be considered in follow-up experiments for either equivocal or negative results. Study parameters that might be modified include the concentration

spacing, and the metabolic activation conditions.

(2) *Evaluation and interpretation of results.* (i) There are several criteria for determining a positive result, such as a concentration-related, or a reproducible increase in mutant frequency. Biological relevance of the results should be considered first. Statistical methods may be used as an aid in evaluating the test results. Statistical significance should not be the only determining factor for a positive response.

(ii) A test substance, for which the results do not meet the criteria described in paragraph (f)(2)(i) of this section is considered non-mutagenic in this system.

(iii) Although most studies will give clearly positive or negative results, in rare cases the data set will preclude making a definite judgement about the activity of the test substance. Results may remain equivocal or questionable regardless of the number of times the experiment is repeated.

(iv) Positive results for an *in vitro* mammalian cell gene mutation test indicate that the test substance induces gene mutations in the cultured mammalian cells used. A positive concentration-response that is reproducible is most meaningful. Negative results indicate that, under the test conditions, the test substance does not induce gene mutations in the cultured mammalian cells used.

(3) *Test report.* The test report shall include the following information:

(i) Test substance:

(A) Identification data and CAS no., if known.

(B) Physical nature and purity.

(C) Physicochemical properties relevant to the conduct of the study.

(D) Stability of the test substance.

(ii) Solvent/vehicle:

(A) Justification for choice of vehicle/solvent.

(B) Solubility and stability of the test substance in solvent/vehicle, if known.

(iii) Cells:

(A) Type and source of cells.

(B) Number of cell cultures.

(C) Number of cell passages, if applicable.

(D) Methods for maintenance of cell cultures, if applicable.

(E) Absence of mycoplasma.

(iv) Test conditions:

(A) Rationale for selection of concentrations and number of cell cultures including e.g., cytotoxicity data and solubility limitations, if available.

(B) Composition of media, CO₂ concentration.

(C) Concentration of test substance.

(D) Volume of vehicle and test substance added.

(E) Incubation temperature.

(F) Incubation time.

(G) Duration of treatment.

(H) Cell density during treatment.

(I) Type and composition of metabolic activation system including acceptability criteria.

(J) Positive and negative controls.

(K) Length of expression period (including number of cells seeded, and subcultures and feeding schedules, if appropriate).

(L) Selective agent(s).

(M) Criteria for considering tests as positive, negative or equivocal.

(N) Methods used to enumerate numbers of viable and mutant cells.

(O) Definition of colonies of which size and type are considered (including criteria for "small" and "large" colonies, as appropriate).

(v) Results:

(A) Signs of toxicity.

(B) Signs of precipitation.

(C) Data on pH and osmolality during the exposure to the test substance, if determined.

(D) Colony size if scored for at least negative and positive controls.

(E) Laboratory's adequacy to detect small colony mutants with the L5178Y TK⁺/- system, where appropriate.

(F) Dose-response relationship, where possible.

(G) Statistical analyses, if any.

(H) Concurrent negative (solvent/vehicle) and positive control data.

(I) Historical negative (solvent/vehicle) and positive control data with ranges, means, and standard deviations.

(J) Mutant frequency.

(vi) Discussion of the results.

(vii) Conclusion.

(g) *References.* For additional background information on this test guideline, the following references should be consulted. These references are available for inspection at the TSCA Nonconfidential Information Center, Rm. NE-B607, Environmental Protection Agency, 401 M St., SW., Washington, DC, 12 noon to 4 p.m., Monday through Friday, except legal holidays.

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§ 799.9538 TSCA mammalian bone marrow chromosomal aberration test.

(a) *Scope*. This section is intended to meet the testing requirements under section 4 of TSCA. The mammalian bone marrow chromosomal aberration test is used for the detection of structural chromosome aberrations induced by test compounds in bone marrow cells of animals, usually rodents. Structural chromosome aberrations may be of two types, chromosome or chromatid. An increase in polyploidy may indicate that a chemical has the potential to induce numerical aberrations. With the majority of chemical mutagens, induced aberrations are of the chromatid-type, but chromosome-type aberrations also occur. Chromosome mutations and related events are the cause of many human genetic diseases and there is substantial evidence that chromosome mutations and related events causing alterations in oncogenes and tumor suppressor genes are involved in cancer in humans and experimental systems.

(b) *Source*. The source material used in developing this TSCA test guideline is the OECD guideline 475 (February 1997). This source is available at the address in paragraph (g) of this section.

(c) *Definitions*. The following definitions apply to this section:

Chromatid-type aberration is structural chromosome damage expressed as breakage of single chromatids or breakage and reunion between chromatids.

Chromosome-type aberration is structural chromosome damage expressed as breakage, or breakage and reunion, of both chromatids at an identical site.

Endoreduplication is a process in which after an S period of DNA replication, the nucleus does not go into mitosis but starts another S period. The

result is chromosomes with 2,4,8,...chromatids.

Gap is an achromatic lesion smaller than the width of one chromatid, and with minimum misalignment of the chromatids.

Numerical aberration is a change in the number of chromosomes from the normal number characteristic of the animals utilized.

Polyploidy is a multiple of the haploid chromosome number (n) other than the diploid number (i.e., 3n, 4n and so on).

Structural aberration is a change in chromosome structure detectable by microscopic examination of the metaphase stage of cell division, observed as deletions and fragments, intrachanges or interchanges.

(d) *Initial considerations*. (1) Rodents are routinely used in this test. Bone marrow is the target tissue in this test, since it is a highly vascularised tissue, and it contains a population of rapidly cycling cells that can be readily isolated and processed. Other species and target tissues are not the subject of this section.

(2) This chromosome aberration test is especially relevant to assessing mutagenic hazard in that it allows consideration of factors of *in vivo* metabolism, pharmacokinetics and DNA-repair processes although these may vary among species and among tissues. An *in vivo* test is also useful for further investigation of a mutagenic effect detected by an *in vitro* test.

(3) If there is evidence that the test substance, or a reactive metabolite, will not reach the target tissue, it is not appropriate to use this test.

(e) *Test method*—(1) *Principle*. Animals are exposed to the test substance by an appropriate route of exposure and are sacrificed at appropriate times after treatment. Prior to sacrifice, animals are treated with a metaphase-arresting agent (e.g., colchicine or Colcemid®). Chromosome preparations are then made from the bone marrow cells and stained, and metaphase cells are analyzed for chromosome aberrations.

(2) *Description*—(i) *Preparations*—(A) *Selection of animal species*. Rats, mice and Chinese hamsters are commonly used, although any appropriate mammalian species may be used. Commonly used laboratory strains of young healthy adult animals should be employed. At the commencement of the study, the weight variation of animals should be minimal and not exceed ± 20% of the mean weight of each sex.

(B) *Housing and feeding conditions*. The temperature in the experimental animal room should be 22°C (± 3°C).

Although the relative humidity should be at least 30% and preferably not exceed 70% other than during room cleaning, the aim should be 50–60%. Lighting should be artificial, the sequence being 12 hrs light, 12 hrs dark. For feeding, conventional laboratory diets may be used with an unlimited supply of drinking water. The choice of diet may be influenced by the need to ensure a suitable admixture of a test substance when administered by this method. Animals may be housed individually, or be caged in small groups of the same sex.

(C) *Preparation of the animals.* Healthy young adult animals shall be randomly assigned to the control and treatment groups. Cages should be arranged in such a way that possible effects due to cage placement are minimized. The animals are identified uniquely. The animals are acclimated to

the laboratory conditions for at least 5 days.

(D) *Preparation of doses.* Solid test substances shall be dissolved or suspended in appropriate solvents or vehicles and diluted, as appropriate, prior to dosing of the animals. Liquid test substances may be dosed directly or diluted prior to dosing. Fresh preparations of the test substance should be employed unless stability data demonstrate the acceptability of storage.

(ii) *Test conditions—(A) Solvent/vehicle.* The solvent/vehicle shall not produce toxic effects at the dose levels used, and shall not be suspected of chemical reaction with the test substance. If other than well-known solvents/vehicles are used, their inclusion should be supported with data indicating their compatibility. It is recommended that wherever possible, the use of an aqueous solvent/vehicle should be considered first.

(B) *Controls.* (1) Concurrent positive and negative (solvent/vehicle) controls shall be included for each sex in each test. Except for treatment with the test substance, animals in the control groups should be handled in an identical manner to the animals in the treated groups.

(2) Positive controls shall produce structural chromosome aberrations *in vivo* at exposure levels expected to give a detectable increase over background. Positive control doses should be chosen so that the effects are clear but do not immediately reveal the identity of the coded slides to the reader. It is acceptable that the positive control be administered by a route different from the test substance and sampled at only a single time. The use of chemical class related positive control chemicals may be considered, when available. Examples of positive control substances include:

Chemical	CAS No.
Triethylenemelamine	[CAS no. 51–18–3]
Ethyl methanesulphonate	[CAS no. 62–50–0]
Ethyl nitrosourea	[CAS no. 759–73–9]
Mitomycin C	[CAS no. 50–07–7]
Cyclophosphamide (monohydrate)	[CAS no. 50–18–0]
	[CAS no. 6055–19–2]

(3) Negative controls, treated with solvent or vehicle alone, and otherwise treated in the same way as the treatment groups, shall be included for every sampling time, unless acceptable inter-animal variability and frequencies of cells with chromosome aberrations are available from historical control data. If single sampling is applied for negative controls, the most appropriate time is the first sampling time. In the absence of historical or published control data demonstrating that no deleterious or mutagenic effects are induced by the chosen solvent/vehicle, untreated controls shall be used.

(3) *Procedure—(i) Number and sex of animals.* Each treated and control group shall include at least 5 analyzable animals per sex. If at the time of the study there are data available from studies in the same species and using the same route of exposure that demonstrate that there are no substantial differences in toxicity between sexes, then testing in a single sex will be sufficient. Where human exposure to chemicals may be sex-specific, as for example with some pharmaceutical agents, the test should

be performed with animals of the appropriate sex.

(ii) *Treatment schedule.* (A) Test substances are preferably administered as a single treatment. Test substances may also be administered as a split dose, i.e. two treatments on the same day separated by no more than a few hrs, to facilitate administering a large volume of material. Other dose regimens should be scientifically justified.

(B) Samples shall be taken at two separate times following treatment on one day. For rodents, the first sampling interval is 1.5 normal cell cycle length (the latter being normally 12–18 hr) following treatment. Since the time required for uptake and metabolism of the test substance as well as its effect on cell cycle kinetics can affect the optimum time for chromosome aberration detection, a later sample collection 24 hr after the first sample time is recommended. If dose regimens of more than one day are used, one sampling time at 1.5 normal cell cycle lengths after the final treatment should be used.

(C) Prior to sacrifice, animals shall be injected intraperitoneally with an appropriate dose of a metaphase

arresting agent (e.g. Colcemid® or colchicine). Animals are sampled at an appropriate interval thereafter. For mice this interval is approximately 3–5 hrs; for Chinese hamsters this interval is approximately 4–5 hrs. Cells shall be harvested from the bone marrow and analyzed from chromosome aberrations.

(iii) *Dose levels.* If a range finding study is performed because there are no suitable data available, it shall be performed in the same laboratory, using the same species, strain, sex, and treatment regimen to be used in the main study (an approach to dose selection is presented in the reference under paragraph (g)(5) of this section). If there is toxicity, three dose levels shall be used for the first sampling time. These dose levels shall cover a range from the maximum to little or no toxicity. At the later sampling time only the highest dose needs to be used. The highest dose is defined as the dose producing signs of toxicity such that higher dose levels, based on the same dosing regimen, would be expected to produce lethality. Substances with specific biological activities at low non-toxic doses (such as hormones and mitogens) may be exceptions to the

dose-setting criteria and should be evaluated on a case-by-case basis. The highest dose may also be defined as a dose that produces some indication of toxicity in the bone marrow (e.g. greater than 50% reduction in mitotic index).

(iv) *Limit test.* If a test at one dose level of at least 2,000 mg/kg body weight using a single treatment, or as two treatments on the same day, produces no observable toxic effects, and if genotoxicity would not be expected based on data from structurally related compounds, then a full study using three dose levels may not be considered necessary. For studies of a longer duration, the limit dose is 2,000 mg/kg/body weight/day for treatment up to 14 days, and 1,000 mg/kg/body weight/day for treatment longer than 14 days. Expected human exposure may indicate the need for a higher dose level to be used in the limit test.

(v) *Administration of doses.* The test substance is usually administered by gavage using a stomach tube or a suitable intubation cannula, or by intraperitoneal injection. Other routes of exposure may be acceptable where they can be justified. The maximum volume of liquid that can be administered by gavage or injection at one time depends on the size of the test animal. The volume should not exceed 2 ml/100g body weight. The use of volumes higher than these must be justified. Except for irritating or corrosive substances which will normally reveal exacerbated effects with higher concentrations, variability in test volume should be minimized by adjusting the concentration to ensure a constant volume at all dose levels.

(vi) *Chromosome preparation.* Immediately after sacrifice, bone marrow shall be obtained, exposed to hypotonic solution and fixed. The cells shall be then spread on slides and stained.

(vii) *Analysis.* (A) The mitotic index should be determined as a measure of cytotoxicity in at least 1,000 cells per animal for all treated animals (including positive controls) and untreated negative control animals.

(B) At least 100 cells should be analyzed for each animal. This number could be reduced when high numbers of aberrations are observed. All slides, including those of positive and negative controls, shall be independently coded before microscopic analysis. Since slide preparation procedures often result in the breakage of a proportion of metaphases with loss of chromosomes, the cells scored should therefore contain a number of centromeres equal to the number $2n \pm 2$.

(f) *Data and reporting—(1) Treatment of results.* Individual animal data shall

be presented in tabular form. The experimental unit is the animal. For each animal the number of cells scored, the number of aberrations per cell and the percentage of cells with structural chromosome aberration(s) shall be evaluated. Different types of structural chromosome aberrations shall be listed with their numbers and frequencies for treated and control groups. Gaps shall be recorded separately and reported but generally not included in the total aberration frequency. If there is no evidence for a difference in response between the sexes, the data may be combined for statistical analysis.

(2) *Evaluation and interpretation of results.* (i) There are several criteria for determining a positive result, such as a dose-related increase in the relative number of cells with chromosome aberrations or a clear increase in the number of cells with aberrations in a single dose group at a single sampling time. Biological relevance of the results should be considered first. Statistical methods may be used as an aid in evaluating the test results (some statistical methods are described in the reference under paragraph (g)(6) of this section). Statistical significance should not be the only determining factor for a positive response. Equivocal results should be clarified by further testing preferably using a modification of experimental conditions.

(ii) An increase in polyploidy may indicate that the test substance has the potential to induce numerical chromosome aberrations. An increase in endoreduplication may indicate that the test substance has the potential to inhibit cell cycle progression. This phenomenon is described in the references under paragraphs (g)(7) and (g)(8) of this section.

(iii) A test substance for which the results do not meet the criteria described in paragraph (f)(2)(i) of this section is considered non-mutagenic in this test.

(iv) Although most experiments will give clearly positive or negative results, in rare cases the data set will preclude making a definite judgment about the activity of the test substance. Results may remain equivocal or questionable regardless of the number of experiments performed.

(v) Positive results from the *in vivo* chromosome aberration test indicate that a substance induces chromosome aberrations in the bone marrow of the species tested. Negative results indicate that, under the test conditions, the test substance does not induce chromosome aberrations in the bone marrow of the species tested.

(vi) The likelihood that the test substance or its metabolites reach the general circulation or specifically the target tissue (e.g., systemic toxicity) should be discussed.

(3) *Test report.* The test report shall include the following information:

(i) Test substance:
(A) Identification data and CAS No., if known.
(B) Physical nature and purity.
(C) Physicochemical properties relevant to the conduct of the study.
(D) Stability of the test substance, if known.
(ii) Solvent/vehicle:
(A) Justification for choice of vehicle.
(B) Solubility and stability of the test substance in solvent/vehicle, if known.
(iii) Test animals:
(A) Species/strain used.
(B) Number, age and sex of animals.
(C) Source, housing conditions, diet, etc.

(D) Individual weight of the animals at the start of the test, including body weight range, mean and standard deviation for each group.

(iv) Test conditions:
(A) Positive and negative (vehicle/solvent) controls.
(B) Data from range-finding study, if conducted.

(C) Rationale for dose level selection.
(D) Details of test substance preparation.

(E) Details of the administration of the test substance.

(F) Rationale for route of administration.

(G) Methods for verifying that the test substance reached the general circulation or target tissue, if applicable.

(H) Conversion from diet/drinking water test substance concentration parts per million (ppm) to the actual dose (mg/kg body weight/day), if applicable.

(I) Details of food and water quality.

(J) Detailed description of treatment and sampling schedules.

(K) Methods for measurement of toxicity.

(L) Identity of metaphase arresting substance, its concentration and duration of treatment.

(M) Methods of slide preparation.

(N) Criteria for scoring aberrations.

(O) Number of cells analyzed per animal.

(P) Criteria for considering studies as positive, negative or equivocal.

(v) Results:

(A) Signs of toxicity.

(B) Mitotic index.

(C) Type and number of aberrations, given separately for each animal.

(D) Total number of aberrations per group with means and standard deviations.

(E) Number of cells with aberrations per group with means and standard deviations.

(F) Changes in ploidy, if seen.

(G) Dose-response relationship, where possible.

(H) Statistical analyses, if any.

(I) Concurrent negative control data.

(J) Historical negative control data with ranges, means and standard deviations.

(K) Concurrent positive control data.

(vi) Discussion of the results.

(vii) Conclusion.

(g) *References.* For additional background information on this test guideline, the following references should be consulted. These references are available for inspection at the TSCA Nonconfidential Information Center, Rm. NE-B607, Environmental Protection Agency, 401 M St., SW., Washington, DC, 12 noon to 4 p.m., Monday through Friday, except legal holidays.

(1) Adler, I.D. Eds. S. Venitt and J.M. Parry. *Cytogenetic Tests in Mammals. Mutagenicity Testing: A Practical Approach.* (IRL Press, Oxford, Washington DC, 1984) pp. 275–306.

(2) Preston, R.J., Dean, B.J., Galloway, S., Holden, H., McFee, A.F., and Shelby, M. *Mammalian In Vivo Cytogenetic Assays: Analysis of Chromosome Aberrations in Bone Marrow Cells.* *Mutation Research.* 189, 157–165 (1987).

(3) Richold, M., Chandley, A., Ashby, J., Gatehouse, D.G., Bootman, J., and Henderson, L. Ed. D.J. Kirkland. *In Vivo Cytogenetic Assays. Basic Mutagenicity Tests, UKEMS Recommended Procedures.* UKEMS Subcommittee on Guidelines for Mutagenicity Testing. Report. Part I revised. (Cambridge University Press, Cambridge, NY, Port Chester, Melbourne, Sydney, 1990) pp. 115–141.

(4) Tice, R.R., Hayashi, M., MacGregor, J.T., Anderson, D., Blakey, D.H., Holden, H.E., Kirsch-Volders, M., Oleson Jr., F.B., Pacchierotti, F., Preston, R.J., Romagna, F., Shimada, H., Sutou, S., and Vannier, B. Report from the Working Group on the *In Vivo* Mammalian Bone Marrow Chromosomal Aberration Test. *Mutation Research.* 312, 305–312 (1994).

(5) Fielder, R.J., Allen, J.A., Boobis, A.R., Botham, P.A., Doe, J., Esdaile, D.J., Gatehouse, D.G., Hodson-Walker, G., Morton, D.B., Kirkland, D. J., and Richold, M. Report of British Toxicology Society/UK Environmental Mutagen Society Working Group: Dose Setting in *In Vivo* Mutagenicity Assays. *Mutagenesis.* 7, 313–319 (1992).

(6) Lovell, D.P., Anderson, D., Albanese, R., Amphlett, G.E., Clare, G.,

Ferguson, R., Richold, M., Papworth, D.G., and Savage, J.R.K. Ed. Kirkland, D. J. *Statistical Analysis of In Vivo Cytogenetic Assays.* UKEMS Subcommittee on Guidelines for Mutagenicity Testing. Report Part III. Statistical Evaluation of Mutagenicity Test Data (Cambridge University Press, Cambridge, 1989) pp. 184–232.

(7) Locke-Huhle, C. Endoreduplication in Chinese Hamster Cells During Alpha-Radiation Induced G2 Arrest. *Mutation Research.* 119, 403–413 (1983).

(8) Huang, Y., Change, C., and Trosko, J. E. Aphidicolin-Induced Endoreduplication in Chinese Hamster Cells. *Cancer Research.* 43, 1362–1364 (1983).

§ 799.9539 TSCA mammalian erythrocyte micronucleus test.

(a) *Scope.* This section is intended to meet the testing requirements under section 4 of TSCA.

(1) The mammalian erythrocyte micronucleus test is used for the detection of damage induced by the test substance to the chromosomes or the mitotic apparatus of erythroblasts by analysis of erythrocytes as sampled in bone marrow and/or peripheral blood cells of animals, usually rodents.

(2) The purpose of the micronucleus test is to identify substances that cause cytogenetic damage which results in the formation of micronuclei containing lagging chromosome fragments or whole chromosomes.

(3) When a bone marrow erythroblast develops into a polychromatic erythrocyte, the main nucleus is extruded; any micronucleus that has been formed may remain behind in the otherwise anucleated cytoplasm. Visualization of micronuclei is facilitated in these cells because they lack a main nucleus. An increase in the frequency of micronucleated polychromatic erythrocytes in treated animals is an indication of induced chromosome damage.

(b) *Source.* The source material used in developing this TSCA test guideline is the OECD guideline 474 (February 1997). This source is available at the address in paragraph (g) of this section.

(c) *Definitions.* The following definitions apply to this section:

Centromere (kinetochore) is a region of a chromosome with which spindle fibers are associated during cell division, allowing orderly movement of daughter chromosomes to the poles of the daughter cells.

Micronuclei are small nuclei, separate from and additional to the main nuclei of cells, produced during telophase of mitosis (meiosis) by lagging

chromosome fragments or whole chromosomes.

Normochromatic erythrocyte is a mature erythrocyte that lacks ribosomes and can be distinguished from immature, polychromatic erythrocytes by stains selective for ribosomes.

Polychromatic erythrocyte is a immature erythrocyte, in an intermediate stage of development, that still contains ribosomes and therefore can be distinguished from mature, normochromatic erythrocytes by stains selective for ribosomes.

(d) *Initial considerations.* (1) The bone marrow of rodents is routinely used in this test since polychromatic erythrocytes are produced in that tissue. The measurement of micronucleated immature (polychromatic) erythrocytes in peripheral blood is equally acceptable in any species in which the inability of the spleen to remove micronucleated erythrocytes has been demonstrated, or which has shown an adequate sensitivity to detect agents that cause structural or numerical chromosome aberrations. Micronuclei can be distinguished by a number of criteria. These include identification of the presence or absence of a kinetochore or centromeric DNA in the micronuclei. The frequency of micronucleated immature (polychromatic) erythrocytes is the principal endpoint. The number of mature (normochromatic) erythrocytes in the peripheral blood that contain micronuclei among a given number of mature erythrocytes can also be used as the endpoint of the assay when animals are treated continuously for 4 weeks or more. This mammalian *in vivo* micronucleus test is especially relevant to assessing mutagenic hazard in that it allows consideration of factors of *in vivo* metabolism, pharmacokinetics and DNA-repair processes although these may vary among species, among tissues and among genetic endpoints. An *in vivo* assay is also useful for further investigation of a mutagenic effect detected by an *in vitro* system.

(2) If there is evidence that the test substance, or a reactive metabolite, will not reach the target tissue, it is not appropriate to use this test.

(e) *Test method—(1) Principle.* Animals are exposed to the test substance by an appropriate route. If bone marrow is used, the animals are sacrificed at appropriate times after treatment, the bone marrow extracted, and preparations made and stained (test techniques described in the references under paragraphs (g)(1), (g)(2), and (g)(3) of this section may be used). When peripheral blood is used, the blood is collected at appropriate times after treatment and smear preparations are

made and stained (the test techniques described in the references under paragraphs (g)(3), (g)(4), (g)(5), and (g)(6) of this section may be used). For studies with peripheral blood, as little time as possible should elapse between the last exposure and cell harvest. Preparations are analyzed for the presence of micronuclei.

(2) *Description*—(i) *Preparations*—(A) *Selection of animal species*. Mice or rats are recommended if bone marrow is used, although any appropriate mammalian species may be used. When peripheral blood is used, mice are recommended. However, any appropriate mammalian species may be used provided it is a species in which the spleen does not remove micronucleated erythrocytes or a species which has shown an adequate sensitivity to detect agents that cause structural or numerical chromosome aberrations. Commonly used laboratory strains of young healthy animals should be employed. At the commencement of the study, the weight variation of animals should be minimal and not exceed $\pm 20\%$ of the mean weight of each sex.

(B) *Housing and feeding conditions*. The temperature in the experimental animal room should be 22°C ($\pm 3^{\circ}\text{C}$). Although the relative humidity should be at least 30% and preferably not

exceed 70% other than during room cleaning, the aim should be 50–60%. Lighting should be artificial, the sequence being 12 hrs light, 12 hrs dark. For feeding, conventional laboratory diets may be used with an unlimited supply of drinking water. The choice of diet may be influenced by the need to ensure a suitable admixture of a test substance when administered by this route. Animals may be housed individually, or caged in small groups of the same sex.

(C) *Preparation of the animals*. Healthy young adult animals shall be randomly assigned to the control and treatment groups. The animals are identified uniquely. The animals are acclimated to the laboratory conditions for at least 5 days. Cages should be arranged in such a way that possible effects due to cage placement are minimized.

(D) *Preparation of doses*. Solid test substances shall be dissolved or suspended in appropriate solvents or vehicles and diluted, if appropriate, prior to dosing of the animals. Liquid test substances may be dosed directly or diluted prior to dosing. Fresh preparations of the test substance should be employed unless stability data demonstrate the acceptability of storage.

(ii) *Test conditions*—(A) *Solvent/vehicle*. The solvent/vehicle should not

produce toxic effects at the dose levels used, and should not be suspected of chemical reaction with the test substance. If other than well-known solvents/vehicles are used, their inclusion shall be supported with reference data indicating their compatibility. It is recommended that wherever possible, the use of an aqueous solvent/vehicle should be considered first.

(B) *Controls*. (1) Concurrent positive and negative (solvent/vehicle) controls shall be included for each sex in each test. Except for treatment with the test substance, animals in the control groups should be handled in an identical manner to animals of the treatment groups.

(2) Positive controls shall produce micronuclei *in vivo* at exposure levels expected to give a detectable increase over background. Positive control doses should be chosen so that the effects are clear but do not immediately reveal the identity of the coded slides to the reader. It is acceptable that the positive control be administered by a route different from the test substance and sampled at only a single time. In addition, the use of chemical class-related positive control chemicals may be considered, when available. Examples of positive control substances include:

Chemical	CAS No.
Ethyl methanesulphonate	[CAS no. 62–50–0]
Ethyl nitrosourea	[CAS no. 759–73–9]
Mitomycin C	[CAS no. 50–07–7]
Cyclophosphamide (monohydrate)	[CAS no. 50–18–0]
	[CAS no. 6055–19–2]
Triethylenemelamine	[CAS no. 51–18–3]

(3) Negative controls, treated with solvent or vehicle alone, and otherwise treated in the same way as the treatment groups shall be included for every sampling time, unless acceptable inter-animal variability and frequencies of cells with micronuclei are demonstrated by historical control data. If single sampling is applied for negative controls, the most appropriate time is the first sampling time. In addition, untreated controls should also be used unless there are historical or published control data demonstrating that no deleterious or mutagenic effects are induced by the chosen solvent/vehicle.

(4) If peripheral blood is used, a pre-treatment sample may also be acceptable as a concurrent negative control, but only in the short peripheral

blood studies (e.g., one to three treatment(s)) when the resulting data are in the expected range for the historical control.

(3) *Procedure*—(i) *Number and sex of animals*. Each treated and control group shall include at least 5 analyzable animals per sex (techniques described in the reference under paragraph (g)(7) of this section may be used). If at the time of the study there are data available from studies in the same species and using the same route of exposure that demonstrate that there are no substantial differences between sexes in toxicity, then testing in a single sex will be sufficient. Where human exposure to chemicals may be sex-specific, as for example with some pharmaceutical

agents, the test should be performed with animals of the appropriate sex.

(ii) *Treatment schedule*. (A) No standard treatment schedule (i.e. one, two, or more treatments at 24 h intervals) can be recommended. The samples from extended dose regimens are acceptable as long as a positive effect has been demonstrated for this study or, for a negative study, as long as toxicity has been demonstrated or the limit dose has been used, and dosing continued until the time of sampling. Test substances may also be administered as a split dose, i.e., two treatments on the same day separated by no more than a few hrs, to facilitate administering a large volume of material.

(B) The test may be performed in two ways:

(1) Animals shall be treated with the test substance once. Samples of bone marrow shall be taken at least twice, starting not earlier than 24 hrs after treatment, but not extending beyond 48 hrs after treatment with appropriate interval(s) between samples. The use of sampling times earlier than 24 hrs after treatment should be justified. Samples of peripheral blood shall be taken at least twice, starting not earlier than 36 hrs after treatment, with appropriate intervals following the first sample, but not extending beyond 72 hrs. When a positive response is recognized at one sampling time, additional sampling is not required.

(2) If two or more daily treatments are used (e.g. two or more treatments at 24 hr intervals), samples shall be collected once between 18 and 24 hrs following the final treatment for the bone marrow and once between 36 and 48 hrs following the final treatment for the peripheral blood (techniques described in the reference under paragraph (g)(8) of this section may be used).

(C) Other sampling times may be used in addition, when relevant.

(iii) *Dose levels.* If a range finding study is performed because there are no suitable data available, it should be performed in the same laboratory, using the same species, strain, sex, and treatment regimen to be used in the main study (guidance on dose setting is provided in the reference in paragraph (g)(9) of this section). If there is toxicity, three dose levels shall be used for the first sampling time. These dose levels shall cover a range from the maximum to little or no toxicity. At the later sampling time only the highest dose needs to be used. The highest dose is defined as the dose producing signs of toxicity such that higher dose levels, based on the same dosing regimen, would be expected to produce lethality. Substances with specific biological activities at low non-toxic doses (such as hormones and mitogens) may be exceptions to the dose-setting criteria and should be evaluated on a case-by-case basis. The highest dose may also be defined as a dose that produces some indication of toxicity in the bone marrow (e.g. a reduction in the proportion of immature erythrocytes among total erythrocytes in the bone marrow or peripheral blood).

(iv) *Limit test.* If a test at one dose level of at least 2,000 mg/kg body weight using a single treatment, or as two treatments on the same day, produces no observable toxic effects, and if genotoxicity would not be expected based upon data from

structurally related substances, then a full study using three dose levels may not be considered necessary. For studies of a longer duration, the limit dose is 2,000 mg/kg/body weight/day for treatment up to 14 days, and 1,000 mg/kg/body weight/day for treatment longer than 14 days. Expected human exposure may indicate the need for a higher dose level to be used in the limit test.

(v) *Administration of doses.* The test substance is usually administered by gavage using a stomach tube or a suitable intubation cannula, or by intraperitoneal injection. Other routes of exposure may be acceptable where they can be justified. The maximum volume of liquid that can be administered by gavage or injection at one time depends on the size of the test animal. The volume should not exceed 2 ml/100g body weight. The use of volumes higher than these must be justified. Except for irritating or corrosive substances which will normally reveal exacerbated effects with higher concentrations, variability in test volume should be minimized by adjusting the concentration to ensure a constant volume at all dose levels.

(vi) *Bone marrow/blood preparation.* Bone marrow cells shall be obtained from the femurs or tibias immediately following sacrifice. Cells shall be removed from femurs or tibias, prepared and stained using established methods. Peripheral blood is obtained from the tail vein or other appropriate blood vessel. Blood cells are immediately stained supravitaly (the test techniques described in the references under paragraphs (g)(4), (g)(5), and (g)(6) of this section may be used) or smear preparations are made and then stained. The use of a DNA specific stain (e.g. acridine orange (techniques described in the reference under paragraph (g)(10) of this section may be used) or Hoechst 33258 plus pyronin-Y) can eliminate some of the artifacts associated with using a non-DNA specific stain. This advantage does not preclude the use of conventional stains (e.g., Giemsa). Additional systems (e.g. cellulose columns to remove nucleated cells (the test techniques described in the references under paragraph (g)(12) of this section may be used)) can also be used provided that these systems have been shown to adequately work for micronucleus preparation in the laboratory.

(vii) *Analysis.* The proportion of immature among total (immature + mature) erythrocytes is determined for each animal by counting a total of at least 200 erythrocytes for bone marrow and 1,000 erythrocytes for peripheral blood (techniques described in the reference under paragraph (g)(13) of this

section maybe used). All slides, including those of positive and negative controls, shall be independently coded before microscopic analysis. At least 2,000 immature erythrocytes per animal shall be scored for the incidence of micronucleated immature erythrocytes. Additional information may be obtained by scoring mature erythrocytes for micronuclei. When analyzing slides, the proportion of immature erythrocytes among total erythrocytes should not be less than 20% of the control value. When animals are treated continuously for 4 weeks or more, at least 2,000 mature erythrocytes per animal can also be scored for the incidence of micronuclei. Systems for automated analysis (image analysis) and cell suspensions (flow cytometry) are acceptable alternatives to manual evaluation if appropriately justified and validated.

(f) *Data and reporting—(1) Treatment of results.* Individual animal data shall be presented in tabular form. The experimental unit is the animal. The number of immature erythrocytes scored, the number of micronucleated immature erythrocytes, and the number of immature among total erythrocytes shall be listed separately for each animal analyzed. When animals are treated continuously for 4 weeks or more, the data on mature erythrocytes should also be given if it is collected. The proportion of immature among total erythrocytes and, if considered applicable, the percentage of micronucleated erythrocytes shall be given for each animal. If there is no evidence for a difference in response between the sexes, the data from both sexes may be combined for statistical analysis.

(2) *Evaluation and interpretation of results.* (i) There are several criteria for determining a positive result, such as a dose-related increase in the number of micronucleated cells or a clear increase in the number of micronucleated cells in a single dose group at a single sampling time. Biological relevance of the results should be considered first. Statistical methods may be used as an aid in evaluating the test results (the test techniques described in the references paragraphs (g)(14) and (g)(15) of this section may be used). Statistical significance should not be the only determining factor for a positive response. Equivocal results should be clarified by further testing preferably using a modification of experimental conditions.

(ii) A test substance for which the results do not meet the criteria described is considered non-mutagenic in this test.

(iii) Although most experiments will give clearly positive or negative results, in rare cases the data set will preclude making a definite judgement about the activity of the test substance. Results, may remain equivocal or questionable regardless of the number of times the experiment is repeated. Positive results in the micronucleus test indicate that a substance induces micronuclei which are the result of chromosomal damage or damage to the mitotic apparatus in the erythroblasts of the test species. Negative results indicate that, under the test conditions, the test substance does not produce micronuclei in the immature erythrocytes of the test species.

(iv) The likelihood that the test substance or its metabolites reach the general circulation or specifically the target tissue (e.g. systemic toxicity) should be discussed.

(3) *Test report.* In addition to the reporting requirements as specified under 40 CFR part 792, subpart J, the following specific information shall be reported. Both individual and summary data should be presented.

(i) Test substance:

(A) Identification data and CAS no., if known.

(B) Physical nature and purity.

(C) Physicochemical properties relevant to the conduct of the study.

(D) Stability of the test substance, if known.

(ii) Solvent/vehicle:

(A) Justification for choice of vehicle.

(B) Solubility and stability of the test substance in the solvent/vehicle, if known.

(iii) Test animals:

(A) Species/strain used.

(B) Number, age, and sex of animals.

(C) Source, housing conditions, diet, etc.

(D) Individual weight of the animals at the start of the test, including body weight range, mean and standard deviation for each group.

(iv) Test conditions:

(A) Positive and negative (vehicle/solvent) control data.

(B) Data from range-finding study, if conducted.

(C) Rationale for dose level selection.

(D) Details of test substance preparation.

(E) Details of the administration of the test substance.

(F) Rationale for route of administration.

(G) Methods for verifying that the test substance reached the general circulation or target tissue, if applicable.

(H) Conversion from diet/drinking water test substance concentration parts per million (ppm) to the actual dose (mg/kg body weight/day), if applicable.

(I) Details of food and water quality.

(J) Detailed description of treatment and sampling schedules.

(K) Methods of slide preparation.

(L) Methods for measurement of toxicity.

(M) Criteria for scoring micronucleated immature erythrocytes.

(N) Number of cells analyzed per animal.

(O) Criteria for considering studies as positive, negative or equivocal.

(v) Results:

(A) Signs of toxicity.

(B) Proportion of immature erythrocytes among total erythrocytes.

(C) Number of micronucleated immature erythrocytes, given separately for each animal.

(D) Mean $\pm$ standard deviation of micronucleated immature erythrocytes per group.

(E) Dose-response relationship, where possible.

(F) Statistical analyses and method applied.

(G) Concurrent and historical negative control data.

(H) Concurrent positive control data.

(vi) Discussion of the results.

(vii) Conclusion.

(g) *References.* For additional background information on this test guideline, the following references should be consulted. These references are available for inspection at the TSCA Nonconfidential Information Center, Rm. NE-B607, Environmental Protection Agency, 401 M St., SW., Washington, DC, 12 noon to 4 p.m., Monday through Friday, except legal holidays.

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§ 799.9620 TSCA neurotoxicity screening battery.

(a) *Scope*. This section is intended to meet the testing requirements under section 4 of TSCA. This neurotoxicity screening battery consists of a functional observational battery, motor activity, and neuropathology. The functional observational battery consists of noninvasive procedures designed to detect gross functional deficits in animals and to better quantify behavioral or neurological effects detected in other studies. The motor activity test uses an automated device that measures the level of activity of an individual animal. The neuropathological techniques are designed to provide data to detect and characterize histopathological changes in the central and peripheral nervous system. This battery is designed to be used in conjunction with general toxicity studies and changes should be evaluated in the context of both the concordance between functional neurological and neuropathological effects, and with respect to any other toxicological effects seen. This test

battery is not intended to provide a complete evaluation of neurotoxicity, and additional functional and morphological evaluation may be necessary to assess completely the neurotoxic potential of a chemical.

(b) *Source*. The source material used in developing this TSCA test guideline is the OPPTS harmonized test guideline 870.6200 (June 1996 Public Draft). This source is available at the address in paragraph (g) of this section.

(c) *Definitions*. The following definitions apply to this section.

ED is effective dose.

Motor activity is any movement of the experimental animal.

Neurotoxicity is any adverse effect on the structure or function of the nervous system related to exposure to a chemical substance.

Toxic effect is an adverse change in the structure or function of an experimental animal as a result of exposure to a chemical substance.

(d) *Principle of the test method*. The test substance is administered to several groups of experimental animals, one dose being used per group. The animals are observed under carefully standardized conditions with sufficient frequency to ensure the detection and quantification of behavioral and/or neurologic abnormalities, if present. Various functions that could be affected by neurotoxicants are assessed during each observation period. Measurements of motor activity of individual animals are made in an automated device. The animals are perfused and tissue samples from the nervous system are prepared for microscopic examination. The exposure levels at which significant neurotoxic effects are produced are compared to one another and to those levels that produce other toxic effects.

(e) *Test procedures*—(1) *Animal selection*—(i) *Species*. In general, the laboratory rat should be used. Under some circumstances, other species, such as the mouse or the dog, may be more appropriate, although not all of the battery may be adaptable to other species.

(ii) *Age*. Young adults (at least 42 days old for rats) shall be used.

(iii) *Sex*. Both males and females shall be used. Females shall be nulliparous and nonpregnant.

(2) *Number of animals*. At least 10 males and 10 females should be used in each dose and control group for behavioral testing. At least five males and five females should be used in each dose and control group for terminal neuropathology. If interim neuropathological evaluations are planned, the number should be increased by the number of animals

scheduled to be perfused before the end of the study. Animals shall be randomly assigned to treatment and control groups.

(3) *Control groups*. (i) A concurrent (vehicle) control group is required. Subjects shall be treated in the same way as for an exposure group except that administration of the test substance is omitted. If the vehicle used has known or potential toxic properties, both untreated or saline treated and vehicle control groups are required.

(ii) Positive control data from the laboratory performing the testing shall provide evidence of the ability of the observational methods used to detect major neurotoxic endpoints including limb weakness or paralysis, tremor, and autonomic signs. Positive control data are also required to demonstrate the sensitivity and reliability of the activity-measuring device and testing procedures. These data should demonstrate the ability to detect chemically induced increases and decreases in activity. Positive control groups exhibiting central nervous system pathology and peripheral nervous system pathology are also required. Separate groups for peripheral and central neuropathology are acceptable (e.g. acrylamide and trimethyl tin). Positive control data shall be collected at the time of the test study unless the laboratory can demonstrate the adequacy of historical data for this purpose, i.e. by the approach outlined in this section.

(4) *Dose level and dose selection*. At least three doses shall be used in addition to the vehicle control group. The data should be sufficient to produce a dose-effect curve. The Agency strongly encourage the use of equally spaced doses and a rationale for dose selection that will maximally support detection of dose-effect relations. For acute studies, dose selection may be made relative to the establishment of a benchmark dose (BD). That is, doses may be specified as successive fractions, e.g. 0.5, 0.25, ...n of the BD. The BD itself may be estimated as the highest nonlethal dose as determined in a preliminary range-finding lethality study. A variety of test methodologies may be used for this purpose, and the method chosen may influence subsequent dose selection. The goal is to use a dose level that is sufficient to be judged a limit dose, or clearly toxic.

(i) *Acute studies*. The high dose need not be greater than 2 g/kg. Otherwise, the high dose should result in significant neurotoxic effects or other clearly toxic effects, but not result in an incidence of fatalities that would preclude a meaningful evaluation of the

data. This dose may be estimated by a BD procedure as described under paragraph (e)(4) of this section, with the middle and low dose levels chosen as fractions of the BD dose. The lowest dose should produce minimal effect, e.g. an ED₁₀, or alternatively, no effects.

(ii) *Subchronic and chronic studies.* The high dose need not be greater than 1 g/kg. Otherwise, the high dose level should result in significant neurotoxic effects or other clearly toxic effects, but not produce an incidence of fatalities that would prevent a meaningful evaluation of the data. The middle and low doses should be fractions of the high dose. The lowest dose should produce minimal effects, e.g. an ED₁₀, or alternatively, no effects.

(5) *Route of exposure.* Selection of route may be based on several criteria including, the most likely route of human exposure, bioavailability, the likelihood of observing effects, practical difficulties, and the likelihood of producing nonspecific effects. For many materials, it should be recognized that more than one route of exposure may be important and that these criteria may conflict with one another. Initially only one route is required for screening for neurotoxicity. The route that best meets these criteria should be selected. Dietary feeding will generally be acceptable for repeated exposures studies.

(6) *Combined protocol.* The tests described in this screening battery may be combined with any other toxicity study, as long as none of the requirements of either are violated by the combination.

(7) *Study conduct—(i) Time of testing.* All animals shall be weighed on each test day and at least weekly during the exposure period.

(A) *Acute studies.* At a minimum, for acute studies observations and activity testing shall be made before the initiation of exposure, at the estimated time of peak effect within 8 hrs of dosing, and at 7 and 14 days after dosing. Estimation of times of peak effect may be made by dosing pairs of rats across a range of doses and making regular observations of gait and arousal.

(B) *Subchronic and chronic studies.* In a subchronic study, at a minimum, observations and activity measurements shall be made before the initiation of exposure and before the daily exposure, or for feeding studies at the same time of day, during the 4th, 8th, and 13th weeks of exposure. In chronic studies, at a minimum, observations and activity measurements shall be made before the initiation of exposure and before the daily exposure, or for feeding studies at the same time of day, every 3 months.

(ii) *Functional observational battery—(A) General conduct.* All animals in a given study shall be observed carefully by trained observers who are unaware of the animals' treatment, using standardized procedures to minimize observer variability. Where possible, it is advisable that the same observer be used to evaluate the animals in a given study. If this is not possible, some demonstration of interobserver reliability is required. The animals shall be removed from the home cage to a standard arena for observation. Effort should be made to ensure that variations in the test conditions are minimal and are not systematically related to treatment. Among the variables that can affect behavior are sound level, temperature, humidity, lighting, odors, time of day, and environmental distractions. Explicit, operationally defined scales for each measure of the battery are to be used. The development of objective quantitative measures of the observational end-points specified is encouraged. Examples of observational procedures using defined protocols may be found in the references under paragraphs (g)(5), (g)(6), and (g)(9) of this section. The functional observational battery shall include a thorough description of the subject's appearance, behavior, and functional integrity. This shall be assessed through observations in the home cage and while the rat is moving freely in an open field, and through manipulative tests. Testing should proceed from the least to the most interactive with the subject. Scoring criteria, or explicitly defined scales, should be developed for those measures which involve subjective ranking.

(B) *List of measures.* The functional observational battery shall include the following list of measures:

(1) Assessment of signs of autonomic function, including but not limited to:

(i) Ranking of the degree of lacrimation and salivation, with a range of severity scores from none to severe.

(ii) Presence or absence of piloerection and exophthalmus.

(iii) Ranking or count of urination and defecation, including polyuria and diarrhea. This is most easily conducted during the open field assessment.

(iv) Pupillary function such as constriction of the pupil in response to light or a measure of pupil size.

(v) Degree of palpebral closure, e.g., ptosis.

(2) Description, incidence, and severity of any convulsions, tremors, or abnormal motor movements, both in the home cage and the open field.

(3) Ranking of the subject's reactivity to general stimuli such as removal from

the cage or handling, with a range of severity scores from no reaction to hyperreactivity.

(4) Ranking of the subject's general level of activity during observations of the unperturbed subject in the open field, with a range of severity scores from unresponsive to hyperactive.

(5) Descriptions and incidence of posture and gait abnormalities observed in the home cage and open field.

(6) Ranking of any gait abnormalities, with a range of severity scores from none to severe.

(7) Forelimb and hindlimb grip strength measured using an objective procedure (the procedure described in the reference under paragraph (g)(8) of this section may be used).

(8) Quantitative measure of landing foot splay (the procedure described in the reference under paragraph (g)(3) of this section may be used).

(9) Sensorimotor responses to stimuli of different modalities will be used to detect gross sensory deficits. Pain perception may be assessed by a ranking or measure of the reaction to a tail-pinch, tail-flick, or hot-plate. The response to a sudden sound, e.g., click or snap, may be used to assess audition.

(10) Body weight.

(11) Description and incidence of any unusual or abnormal behaviors, excessive or repetitive actions (stereotypies), emaciation, dehydration, hypotonia or hypertonia, altered fur appearance, red or crusty deposits around the eyes, nose, or mouth, and any other observations that may facilitate interpretation of the data.

(C) *Additional measures.* Other measures may also be included and the development and validation of new tests is encouraged. Further information on the neurobehavioral integrity of the subject may be provided by:

(1) Count of rearing activity on the open field.

(2) Ranking of righting ability.

(3) Body temperature.

(4) Excessive or spontaneous vocalizations.

(5) Alterations in rate and ease of respiration, e.g., rales or dyspnea.

(6) Sensorimotor responses to visual or proprioceptive stimuli.

(iii) *Motor activity.* Motor activity shall be monitored by an automated activity recording apparatus. The device used must be capable of detecting both increases and decreases in activity, i.e., baseline activity as measured by the device must not be so low as to preclude detection of decreases nor so high as to preclude detection of increases in activity. Each device shall be tested by standard procedures to ensure, to the extent possible, reliability of operation

across devices and across days for any one device. In addition, treatment groups must be balanced across devices. Each animal shall be tested individually. The test session shall be long enough for motor activity to approach asymptotic levels by the last 20% of the session for nontreated control animals. All sessions shall have the same duration. Treatment groups shall be counterbalanced across test times. Effort should be made to ensure that variations in the test conditions are minimal and are not systematically related to treatment. Among the variables which can affect motor activity are sound level, size and shape of the test cage, temperature, relative humidity, lighting conditions, odors, use of the home cage or a novel test cage, and environmental distractions.

(iv) *Neuropathology: Collection, processing and examination of tissue samples.* To provide for adequate sampling as well as optimal preservation of cellular integrity for the detection of neuropathological alterations, tissue shall be prepared for histological analysis using in situ perfusion and paraffin and/or plastic embedding procedures. Paraffin embedding is acceptable for tissue samples from the central nervous system. Plastic embedding of tissue samples from the central nervous system is encouraged, when feasible. Plastic embedding is required for tissue samples from the peripheral nervous system. Subject to professional judgment and the type of neuropathological alterations observed, it is recommended that additional methods, such as glial fibrillary acidic protein (GFAP) immunohistochemistry and/or methods known as Bodian's or Bielchowsky's silver methods be used in conjunction with more standard stains to determine the lowest dose level at which neuropathological alterations are observed. When new or existing data provide evidence of structural alterations it is recommended that the GFAP immunoassay also be considered. A description of this technique can be found in the reference under paragraph (g)(10) of this section.

(A) *Fixation and processing of tissue.* The nervous system shall be fixed by in situ perfusion with an appropriate aldehyde fixative. Any gross abnormalities should be noted. Tissue samples taken should adequately represent all major regions of the nervous system. The tissue samples should be postfixed and processed according to standardized published histological protocols (protocols described in the references under paragraphs (g)(1), (g)(2), or (g)(11) of this

section may be used). Tissue blocks and slides should be appropriately identified when stored. Histological sections should be stained for hematoxylin and eosin (H&E), or a comparable stain according to standard published protocols (some of these protocols are described in the references under paragraphs (g)(1) and (g)(11) of this section).

(B) *Qualitative examination.* Representative histological sections from the tissue samples should be examined microscopically by an appropriately trained pathologist for evidence of neuropathological alterations. The nervous system shall be thoroughly examined for evidence of any treatment-related neuropathological alterations. Particular attention should be paid to regions known to be sensitive to neurotoxic insult or those regions likely to be affected based on the results of functional tests. Such treatment-related neuropathological alterations should be clearly distinguished from artifacts resulting from influences other than exposure to the test substance. A stepwise examination of tissue samples is recommended. In such a stepwise examination, sections from the high dose group are first compared with those of the control group. If no neuropathological alterations are observed in samples from the high dose group, subsequent analysis is not required. If neuropathological alterations are observed in samples from the high dose group, samples from the intermediate and low dose groups are then examined sequentially.

(C) *Subjective diagnosis.* If any evidence of neuropathological alterations is found in the qualitative examination, then a subjective diagnosis shall be performed for the purpose of evaluating dose-response relationships. All regions of the nervous system exhibiting any evidence of neuropathological changes should be included in this analysis. Sections from all dose groups from each region will be coded and examined in randomized order without knowledge of the code. The frequency of each type and severity of each lesion will be recorded. After all samples from all dose groups including all regions have been rated, the code will be broken and statistical analysis performed to evaluate dose-response relationships. For each type of dose-related lesion observed, examples of different degrees of severity should be described. Photomicrographs of typical examples of treatment-related regions are recommended to augment these descriptions. These examples will also serve to illustrate a rating scale, such as 1+, 2+, and 3+ for the degree of severity

ranging from very slight to very extensive.

(f) *Data reporting and evaluation.* The final test report shall include the following information:

(1) *Description of equipment and test methods.* A description of the general design of the experiment and any equipment used shall be provided. This shall include a short justification explaining any decisions involving professional judgment.

(i) A detailed description of the procedures used to standardize observations, including the arena and scoring criteria.

(ii) Positive control data from the laboratory performing the test that demonstrate the sensitivity of the procedures being used. Historical data may be used if all essential aspects of the experimental protocol are the same. Historical control data can be critical in the interpretation of study findings. The Agency encourages submission of such data to facilitate the rapid and complete review of the significance of effects seen.

(2) *Results.* The following information shall be arranged by test group dose level.

(i) In tabular form, data for each animal shall be provided showing:

(A) Its identification number.

(B) Its body weight and score on each sign at each observation time, the time and cause of death (if appropriate), total session activity counts, and intrasession subtotals for each day measured.

(ii) Summary data for each group must include:

(A) The number of animals at the start of the test.

(B) The number of animals showing each observation score at each observation time.

(C) The mean and standard deviation for each continuous endpoint at each observation time.

(D) Results of statistical analyses for each measure, where appropriate.

(iii) All neuropathological observations shall be recorded and arranged by test groups. This data may be presented in the following recommended format:

(A) *Description of lesions for each animal.* For each animal, data must be submitted showing its identification (animal number, sex, treatment, dose, and duration), a list of structures examined as well as the locations, nature, frequency, and severity of lesions. Inclusion of photomicrographs is strongly recommended for demonstrating typical examples of the type and severity of the neuropathological alterations observed. Any diagnoses derived from

neurological signs and lesions including naturally occurring diseases or conditions, should be recorded.

(B) *Counts and incidence of neuropathological alterations by test group.* Data should be tabulated to show:

(1) The number of animals used in each group and the number of animals in which any lesion was found.

(2) The number of animals affected by each different type of lesion, the locations, frequency, and average grade of each type of lesion.

(3) *Evaluation of data.* The findings from the screening battery should be evaluated in the context of preceding and/or concurrent toxicity studies and any correlated functional and histopathological findings. The evaluation shall include the relationship between the doses of the test substance and the presence or absence, incidence and severity, of any neurotoxic effects. The evaluation shall include appropriate statistical analyses, for example, parametric tests for continuous data and nonparametric tests for the remainder. Choice of analyses should consider tests appropriate to the experimental design, including repeated measures. There may be many acceptable ways to analyze data.

(g) *References.* For additional background information on this test guideline, the following references should be consulted. These references are available for inspection at the TSCA Nonconfidential Information Center, Rm. NE-B607, Environmental Protection Agency, 401 M St., SW., Washington, DC, 12 noon to 4 p.m., Monday through Friday, except legal holidays.

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§ 799.9780 TSCA immunotoxicity.

(a) *Scope.* This section is intended to meet the testing requirements under section 4 of TSCA. This section is intended to provide information on suppression of the immune system which might occur as a result of repeated exposure to a test chemical. While some information on potential immunotoxic effects may be obtained from hematology, lymphoid organ weights and histopathology (usually done as part of routine toxicity testing), there are data which demonstrate that these endpoints alone are not sufficient to predict immunotoxicity (Luster *et al.*, 1992, 1993 see paragraphs (j)(8) and (j)(9) of this section). Therefore, the tests

described in this section are intended to be used along with data from routine toxicity testing, to provide more accurate information on risk to the immune system. The tests in this section do not represent a comprehensive assessment of immune function.

(b) *Source.* The source material used in developing this TSCA test guideline is the OPPTS harmonized test guideline 870.7800 (June 1996 Public Draft). This source is available at the address in paragraph (j) of this section.

(c) *Definitions.* The following definitions apply to this section.

Antibodies or immunoglobulins (Ig) are part of a large family of glycoprotein molecules. They are produced by B cells in response to antigens, and bind specifically to the eliciting antigen. The different classes of immunoglobulins involved in immunity are IgG, IgA, IgM, IgD, and IgE. Antibodies are found in extracellular fluids, such as serum, saliva, milk, and lymph. Most antibody responses are T cell-dependent, that is, functional T and B lymphocytes, as well as antigen-presenting cells (usually macrophages), are required for the production of antibodies.

Cluster of differentiation (CD) refers to molecules expressed on the cell surface. These molecules are useful as distinct CD molecules are found on different populations of cells of the immune system. Antibodies against these cell surface markers (e.g., CD4, CD8) are used to identify and quantitate different cell populations.

Immunotoxicity refers to the ability of a test substance to suppress immune responses that could enhance the risk of infectious or neoplastic disease, or to induce inappropriate stimulation of the immune system, thus contributing to allergic or autoimmune disease. This section only addresses potential immune suppression.

Natural Killer (NK) cells are large granular lymphocytes which nonspecifically lyse cells bearing tumor or viral antigens. NK cells are up-regulated soon after infection by certain microorganisms, and are thought to represent the first line of defense against viruses and tumors.

T and B cells are lymphocytes which are activated in response to specific antigens (foreign substances, usually proteins). B cells produce antigen-specific antibodies (see the definition for "antibodies or immunoglobulins"), and subpopulations of T cells are frequently needed to provide help for the antibody response. Other types of T cell participate in the direct destruction of cells expressing specific foreign

(tumor or infectious agent) antigens on the cell surface.

(d) *Principles of the test methods.* (1) In order to obtain data on the functional responsiveness of major components of the immune system to a T cell dependent antigen, sheep red blood cells (SRBC), rats and/or mice¹ shall be exposed to the test and control substances for at least 28 days.² The animals shall be immunized by intravenous or intraperitoneal injection of SRBCs approximately 4 days (depending on the strain of animal) prior to the end of the exposure. At the end of the exposure period, either the plaque forming cell (PFC) assay or an enzyme linked immunosorbent assay (ELISA) shall be performed to determine the effects of the test substance on the splenic anti-SRBC (IgM) response or serum anti-SRBC IgM levels, respectively.

(2) In the event the test substance produces significant suppression of the anti-SRBC response, expression of phenotypic markers for major lymphocyte populations (total T and total B), and T cell subpopulations (T helpers (CD⁴) and T cytotoxic/suppressors (CD⁸)), as assessed by flow cytometry, may be performed to determine the effects of the test substance on either splenic or peripheral-blood lymphocyte populations and T cell subpopulations. When this study is performed, the appropriate monoclonal antibodies for the species being tested should be used. If the test substance has no significant effect on the anti-SRBC assay, a functional test for NK cells may be performed to test for a chemical's effect on non-specific immunity.³ For tests performed using cells or sera from blood (ELISA or flow cytometry), it is not necessary to destroy the animals, since immunization with SRBCs at 28 days is not expected to markedly affect the results of other assays included in subchronic or longer-term studies (these tests are discussed in the reference under paragraph (j)(7) of this section). The necessity to perform either a quantitative analysis of the effects of a chemical on the numbers of cells in

major lymphocyte populations and T Cell subpopulations by flow cytometry, or a splenic NK cell activity assay to assess the effects of the test compound on non-specific immunity shall be determined on a case-by-case basis, depending upon the outcome of the anti-SRBC assay.

(e) *Limit test.* If a test at one dose level of at least 1,000 mg/kg body weight (or 2 mg/L for inhalation route of exposure) using the procedures described for this study produces no observable toxic effects or if toxic effects would not be expected based upon data of structurally related compounds, then a full study using three dose levels might not be necessary. Expected human exposure may indicate the need for a higher dose level.

(f) *Test procedures—(1) Animal selection—(i) Species and strain.* These tests are intended for use in rats and/or mice. Commonly used laboratory strains shall be employed.⁴ All test animals shall be free of pathogens, internal and external parasites. Females shall be nulliparous and nonpregnant. The species, strain, and source of the animals shall be identified.

(ii) *Age/weight.* (A) Young, healthy animals shall be employed. At the commencement of the study, the weight variation of the animals used shall not exceed $\pm 20\%$ of the mean weight for each sex.

(B) Dosing shall begin when the test animals are between 6 and 8 weeks old.

(iii) *Sex.* Either sex may be used in the study; if one sex is known or believed to be more sensitive to the test compound, then that sex shall be used.

(iv) *Numbers.* (A) At least eight animals shall be included in each dose and control group. The number of animals tested shall yield sufficient statistical power to detect a 20% change based upon the interanimal variation which may be encountered in these assays.

(B) To avoid bias, the use of adequate randomization procedures for the proper allocation of animals to test and control groups is required.

(C) Each animal shall be assigned a unique identification number. Dead animals, their preserved organs and tissues, and microscopic slides shall be identified by reference to the animal's unique number.

(v) *Husbandry.* (A) Animals may be group-caged by sex, but the number of animals per cage shall not interfere with

clear observation of each animal. The biological properties of the test substance or toxic effects (e.g., morbidity, excitability) may indicate a need for individual caging.

(B) The temperature of the experimental animal rooms shall be at $22 \pm 3^\circ\text{C}$.

(C) The relative humidity of the experimental animal rooms shall be between 30 and 70%.

(D) Where lighting is artificial, the sequence shall be 12 hrs light, 12 hrs dark.

(E) Control and test animals shall be maintained on the same type of bedding and receive feed from the same lot. The feed shall be analyzed to assure adequacy of nutritional requirements of the species tested and for impurities that might influence the outcome of the test. Rodents shall be fed and watered *ad libitum* with food replaced at least weekly.

(F) The study shall not be initiated until the animals have been allowed an adequate period of acclimatization or quarantine to environmental conditions. The period of acclimatization shall be at least 1 week in duration.

(2) *Control and test substances.* (i) The test substance shall be dissolved or suspended in a suitable vehicle. Ideally, if a vehicle or diluent is needed, it shall not elicit toxic effects or substantially alter the chemical or toxicological properties of the test substance. It is recommended that an aqueous solution should be used. If solubility is a problem a solution in oil may be used. Other vehicles may be considered, but only as a last resort.

(ii) One lot of the test substance shall be used, if possible, throughout the duration of the study, and the research sample shall be stored under conditions that maintain its purity and stability. Prior to the initiation of the study, there shall be a characterization of the test substance, including the purity of the test compound and if technically feasible, the name and quantities of any known contaminants and impurities.

(iii) If the test or positive control substance is to be incorporated into feed or another vehicle, the period during which the test substance is stable in such a mixture shall be determined prior to the initiation of the study. Its homogeneity and concentration shall also be determined prior to the initiation of the study and periodically during the study. Statistically randomized samples of the mixture shall be analyzed to ensure that proper mixing, formulation, and storage procedures are being followed, and that the appropriate concentration of the test

¹ If absorption/distribution/metabolism/excretion (ADME) data are similar between species, then either rats or mice may be used for the test compound in question. If such data are lacking, both species should be used.

² Because there is a fairly rapid turnover of many of the cells in the immune system, 28 days is considered sufficient for the purposes of the anti-SRBC tests.

³ When these optional tests are included, the phenotypic or NK cell analyses may be performed at 28 days of exposure, or at a later timepoint if ADME data suggest that a longer exposure is more appropriate.

⁴ The study director shall be aware of strain differences in response to SRBC. For example, if the B₆C₃F₁ hybrid mouse is used in the PFC assay, a response of 800–1,000 PFC/10⁶ spleen cells in control mice should be the minimally acceptable PFC response.

or control substance is contained in the mixture.

(3) *Control groups.* (i) A concurrent, vehicle-treated control group is required.

(ii) A separate untreated control group is required if the toxicity of the vehicle is unknown.

(iii) A positive control group with a known immunosuppressant (e.g., cyclophosphamide) shall be included in the study. A group of at least eight animals shall be given the immunosuppressive chemical.

(4) *Dose levels.* (i) In repeated-dose toxicity tests, it is desirable to have a dose-response relationship and a no observed immunotoxic effect level. Therefore, at least three dose levels and a negative control shall be used, unless a limit test is performed as specified under paragraph (e) of this section.

(ii) The highest dose level shall not produce significant stress, malnutrition, or fatalities, but ideally should produce some measurable sign of general toxicity (e.g., a 10% loss of body weight).

(iii) The lowest dose level ideally shall not produce any evidence of immunotoxicity.

(5) *Administration of the test substance.* (i) The test substance, vehicle, or positive control substance shall be administered for at least 28 days for the anti-SRBC assay. The route of administration of the test material will usually be oral; however, this shall be determined by the likely route of occupational or indoor exposure. Therefore, under certain conditions, the dermal or inhalation route of exposure may be more relevant for the study. All animals shall be dosed by the same method during the entire experimental period.

(ii) If the test substance is administered by gavage, the animals are dosed with the test substance ideally on a 7-days-per-week basis. However, based primarily on practical considerations, dosing by gavage on a 5-days-per-week basis shall be acceptable. If the test substance is administered in the drinking water, or mixed directly into the diet, then exposure shall be on a 7-days-per-week basis.

(A) For substances of low toxicity, it is important to ensure that when administered in the diet, the quantities of the test substance involved do not interfere with normal nutrition. When the test substance is administered in the diet, either a constant dietary concentration in parts per million (ppm) or a constant dose level in terms of the animal's body weight shall be used; the alternative used should be specified.

(B) For a substance administered by gavage, the dose shall be given at

approximately the same time each day, and adjusted at intervals (weekly for mice, twice per week for rats) to maintain a constant dose level in terms of the animal's body weight.

(iii) If the test substance is administered dermally, use paragraphs (f)(5)(iii)(A) through (f)(5)(iii)(D) of this section.

(A) *Dose levels and dose selection.* (1) In this test, it is desirable to determine a dose-response relationship as well as a NOEL. Therefore, at least three dose levels plus a control and, where appropriate, a vehicle control (corresponding to the concentration of vehicle at the highest dose level) group should be used. Doses should be spaced appropriately to produce test groups with a range of toxic effects. The data should be sufficient to produce a dose-response curve.

(2) The highest dose level should elicit signs of toxicity but not produce severe skin irritation or an incidence of fatality which would prevent a meaningful evaluation. If application of the test substance produces severe skin irritation, the concentration may be reduced, although this may result in a reduction in, or absence of, other toxic effects at the high dose level. If the skin has been badly damaged early in the study, it may be necessary to terminate the study and undertake a new one at lower concentrations.

(3) The intermediate dose levels should be spaced to produce a gradation of toxic effects.

(4) The lowest dose level should not produce any evidence of toxic effects.

(B) *Preparation of animal skin.* Shortly before testing, fur should be clipped from not less than 10% of the body surface area for application of the test substance. In order to dose approximately 10% of the body surface, the area starting at the scapulae (shoulders) to the wing of the ileum (hipbone) and half-way down the flank on each side of the animal should be shaved. Shaving should be carried out approximately 24 hrs before dosing. Repeated clipping or shaving is usually needed at approximately weekly intervals. When clipping or shaving the fur, care should be taken to avoid abrading the skin which could alter its permeability.

(C) *Preparation of test substance.* (1) Liquid test substances are generally used undiluted, except as indicated in paragraph (f)(5)(iii)(A)(2) of this section.

(2) Solids should be pulverized when possible. The substance should be moistened sufficiently with water or, when necessary, a suitable vehicle to ensure good contact with the skin. When a vehicle is used, the influence of

the vehicle on toxicity of, and penetration of the skin by, the test substance should be taken into account.

(3) The volume of application should be kept constant, e.g. less than 300 μ L for the rat; different concentrations of test solution should be prepared for different dose levels.

(D) *Administration of test substance.*

(1) The duration of exposure should be at least for 90 days.

(2) The animals should be treated with test substance for at least 6 hrs/day on a 7-day per week basis. However, based on practical considerations, application on a 5-day per week basis is acceptable. Dosing should be conducted at approximately the same time each day.

(3) The test substance should be applied uniformly over the treatment site.

(4) The surface area covered may be less for highly toxic substances. As much of the area should be covered with as thin and uniform a film as possible.

(5) During the exposure period, the test substance should be held in contact with the skin with a porous gauze dressing. The test site should be further covered with nonirritating tape to retain the gauze dressing and the test substance and to ensure that the animals cannot ingest the test substance. Restraint may be used to prevent the ingestion of the test substance, but complete immobilization is not recommended.

(iv) If the test substance is administered by the inhalation route, use the procedures under paragraphs (e)(2), (e)(3), (e)(6), (e)(8), (e)(9), and (e)(10) of 40 CFR 799.9346. The exposure time for the anti-SRBC test shall be at least 28 days.

(6) *Observation period.* Duration of the observation period shall be at least 28 days.

(7) *Observation of animals.* (i) Observations shall be made at least once each day for morbidity and mortality. Appropriate actions shall be taken to minimize loss of animals to the study (e.g., necropsy of those animals found dead and isolation or euthanasia of weak or moribund animals).

(ii) A careful clinical examination shall be made at least once a week. Observations shall be detailed and carefully recorded, preferably using explicitly defined scales. Observations shall include, but not be limited to: evaluation of skin and fur, eyes and mucous membranes; respiratory and circulatory effects; autonomic effects, such as salivation; central nervous system effects, including tremors and convulsions, changes in the level of

motor activity, gait and posture, reactivity to handling or sensory stimuli, grip strength, and stereotypes or bizarre behavior (e.g., self-mutilation, walking backwards).

(iii) Signs of toxicity shall be recorded as they are observed, including the time of onset, degree and duration.

(iv) Food and water consumption shall be determined weekly.

(v) Animals shall be weighed immediately prior to dosing, weekly (twice per week for rats) thereafter, and just prior to euthanasia.

(vi) Any moribund animals shall be removed and euthanized when first noticed. Necropsies shall be conducted on all moribund animals, and on all animals that die during the study.

(vii) The spleen and thymus shall be weighed in all animals at the end of the study.

(g) *Immunotoxicity tests*—(1) *Functional tests.* Either a splenic PFC assay or an ELISA shall be used to determine the response to antigen administration.

(i) *Antibody plaque-forming cell (PFC) assay.* If the antibody PFC assay is performed, the criteria listed under paragraphs (g)(1)(i)(A) through (g)(1)(i)(F) of this section shall be adhered to. Assays described in the references under paragraphs (j)(2) and (j)(4) of this section may be used.

(A) The T cell-dependent antigen, SRBC, shall be injected intravenously or intraperitoneally, usually at 24 days after the first dosing with the test substance.⁵ Although the optimum response time is usually 4 days after immunization, some strains of test animal may deviate from this time point. The strain to be used shall be evaluated for the optimum day for PFC formation after immunization.

(B) The activity of each new batch of complement shall be determined. For any given study, the SRBCs shall be from a single sheep, or pool of sheep, for which the shelf life and dose for optimum response has been determined.

(C) Modifications of the PFC assay described in paragraph (g)(1)(i) of this section exist and may prove useful; however, the complete citation shall be made for the method used, any modifications to the method shall be reported, and the source and, where appropriate, the activity or purity of important reagents shall be given. Justification or rationale shall be provided for each protocol modification. Discussions of modifications of the PFC

assay are available in the references under paragraphs (j)(5), (j)(6), and (j)(10) of this section.

(D) Samples shall be randomized and shall be coded for PFC analysis, so that the analyst is unaware of the treatment group of each sample examined.

(E) Spleen cell viability shall be determined.

(F) The numbers of IgM PFC per spleen, and the number of IgM PFC per 10⁶ spleen cells shall be reported.

(ii) *Immunoglobulin quantification.* As an alternative to a PFC assay, the effects of the test substance on the antibody response to antigen may be determined by an Enzyme-Linked Immunosorbent Assay (ELISA). Comparison between the PFC and ELISA assays for immunotoxicity assessment are discussed in the references under paragraphs (j)(5), (j)(6), and (j)(10) of this section. Test animals shall be immunized with SRBCs as for the PFC assay. IgM titers in the serum of each test animal shall be determined (usually 4 days after immunization). As with the PFC assay, the optimum dose of SRBCs and optimum time for collection of the sera shall be determined for the species and strain of animal to be tested. Several methods are described in the reference under paragraph (j)(11) of this section.

(iii) *Natural killer (NK) cell activity.* The methods described in the reference under paragraph (j)(3) of this section may be used to demonstrate the effects of at least 28 days of exposure to a test substance on spontaneous cytotoxic activity. In this assay, splenocytes from treated and untreated test animals are incubated with ⁵¹Cr-labeled YAC-1 lymphoma cells. The amount of radiolabel released from the target cells after incubation with the effector cells for four hrs is used as a measure of NK cytolysis. The following points shall be adhered to when using the NK cell assay:

(A) Assay controls shall be included to account for spontaneous release of radiolabel from target cells in the absence of effector cells, and also for the determination of total release of radiolabel.

(B) Target cells other than YAC-1 lymphoma cells may be appropriate for use in the assay. In all cases, target cell viability shall be determined.

(C) Modifications of the protocol exist that may prove useful. However, complete citation shall be made to the method used. Modifications shall be reported, and where appropriate, the source, activity, and/or purity of the reagents should be given. Justification or rationale shall be provided for each protocol modification.

(2) *Enumeration of splenic or peripheral blood total B cells, total T cells, and T cell subpopulations.* The phenotypic analysis of total B cell, total T cell, and T cell subpopulations from the spleen or peripheral blood by flow cytometry should be performed after at least 28 days of dosing; this may be performed at a later timepoint, if ADME data suggest that a longer exposure is more appropriate. If an exposure period longer than 28 days is used, then these tests may be performed in conjunction with subchronic (ninety day oral, dermal, or inhalation) toxicity studies, when these studies are required. Methods described in the references under paragraphs (j)(1) and (j)(5) of this section may be used.

(h) *Data and reporting*—(1) *Treatment of results*—(i) Data shall be summarized in tabular form, showing for each test group the number of animals at the start of the test, the number of animals showing effects, the types of effects and the percentage of animals displaying each type of effect.

(ii) All observed results, quantitative and incidental, shall be evaluated by an appropriate statistical method. Any generally accepted statistical methods may be used; the statistical methods including significance criteria shall be selected during the design of the study.

(2) *Evaluation of study results.* The findings of an immunotoxicity study shall be evaluated in conjunction with the findings of preceding studies and considered in terms of other toxic effects. The evaluation shall include the relationship between the dose of the test substance and the presence or absence, and the incidence and severity of abnormalities, including behavioral and clinical abnormalities, gross lesions, identified target organs, body weight changes, effects on mortality and any other general or specific toxic effects. A properly conducted test shall provide a satisfactory estimation of a no-observed-effect level. It may indicate the need for an additional study and provide information on the selection of dose levels.

(3) *Test report.* In addition to the reporting requirements as specified under 40 CFR part 792, subpart J, the following specific information shall be reported. Both individual and summary data should be presented.

(i) The test substance characterization shall include:

(A) Chemical identification.

(B) Lot or batch number.

(C) Physical properties.

(D) Purity/impurities.

(E) Identification and composition of any vehicle used.

⁵ If the SRBCs are administered by the intraperitoneal route, the study director should be aware that a low percentage of animals may not respond because the antigen was accidentally injected into the intestinal tract.

(ii) The test system shall contain data on:

(A) Species, strain, and rationale for selection of animal species, if other than that recommended.

(B) Age, body weight data, and sex.

(C) Test environment including cage conditions, ambient temperature, humidity, and light/dark periods.

(D) When inhalation is the route of exposure, a description of the exposure equipment and data shall be included as follows:

(1) Description of test conditions; the following exposure conditions shall be reported:

(i) Description of exposure apparatus including design, type, volume, source of air, system for generating aerosols, method of conditioning air, treatment of exhaust air and the method of housing the animals in a test chamber.

(ii) The equipment for measuring temperature, humidity, and particulate aerosol concentrations and size should be described.

(2) Exposure data shall be tabulated and presented with mean values and a measure of variability (e.g., standard deviation) and include:

(i) Airflow rates through the inhalation equipment.

(ii) Temperature and humidity of air.

(iii) Actual (analytical or gravimetric) concentration in the breathing zone.

(iv) Nominal concentration (total amount of test substance fed into the inhalation equipment divided by volume of air).

(v) Particle size distribution, calculated mass median aerodynamic diameter (MMAD) and geometric standard deviation (GSD).

(vi) Explanation as to why the desired chamber concentration and/or particle size could not be achieved (if applicable) and the efforts taken to comply with this aspect of the section.

(E) Identification of animal diet.

(iii) The test procedure shall include the following data:

(A) Method of randomization used.

(B) Full description of experimental design and procedure.

(C) Dose regimen including levels, methods, and volume.

(iv) Test results should include the following data:

(A) Group animal toxic response data shall be tabulated by species, strain, sex, and exposure level for:

(1) Number of animals exposed.

(2) Number of animals showing signs of toxicity.

(3) Number of animals dying.

(B) Individual animal data shall be presented, as well as summary (group mean data).

(C) Date of death during the study or whether animals survived to termination.

(D) Date of observation of each abnormal sign and its subsequent course.

(E) Absolute and relative spleen and thymus weight data.

(F) Feed and water consumption data, when collected.

(G) Results of immunotoxicity tests.

(H) Necropsy findings of animals that were found moribund and euthanized or died during the study.

(I) Statistical treatment of results, where appropriate.

(i) *Quality control.* A system shall be developed and maintained to assure and document adequate performance of laboratory staff and equipment. The study shall be conducted in compliance with the 40 CFR Part 792—Good Laboratory Practice.

(j) *References.* For additional background information on this test guideline, the following references should be consulted. These references are available for inspection at the TSCA Nonconfidential Information Center, Rm. NE-B607, Environmental Protection Agency, 401 M St., SW., Washington, DC, 12 noon to 4 p.m., Monday through Friday, except legal holidays.

(1) Cornacoff, J.B., Graham, C.S., and LaBrie, T.K. Eds. Burleson, G.R., Dean, J.H., and Munson, A.E. Phenotypic identification of peripheral blood mononuclear leukocytes by flow cytometry as an adjunct to immunotoxicity evaluation. Vol. 1. *Methods in Immunotoxicology* (Wiley-Liss, Inc., New York, 1995) pp. 211–226.

(2) Cunningham, A.J. A method of increased sensitivity for detecting single antibody-forming cells. *Nature*. 207:1106–1107 (1965).

(3) Djeu, Julie Y. Eds. Burleson, G.R., Dean, J.H., and Munson, A.E. Natural Killer Activity. *Methods in Immunotoxicology*. pp. 437–449 (1995).

(4) Holsapple, M.P. Eds. Burleson, G.R., Dean, J.H., and Munson, A.E. The plaque-forming cell (PFC) response in Immunotoxicology: An approach to monitoring the primary effector function

of B lymphocytes. Vol. 1. *Methods in Immunotoxicology* (Wiley-Liss, Inc., New York, 1995) pp. 71–108.

(5) Ladics, G.S. and Loveless, S.E. Cell surface marker analysis of splenic lymphocyte populations of the CD rat for use in immunotoxicological studies. *Toxicology Methods*. 4: 77–91 (1994).

(6) Ladics, G.S., Smith, C., Heaps, K., and Loveless, S.E. Evaluation of the humoral immune response of CD rats following a 2-week exposure to the pesticide carbaryl by the oral, dermal, or inhalation routes. *Journal of Toxicology Environmental Health*. 42:143–156 (1994).

(7) Ladics, G.S., Smith, C., Heaps, K., Elliot, G.S., Slone, T.W., and Loveless, S.E. Possible incorporation of an immunotoxicological functional assay for assessing humoral immunity for hazard identification purposes in rats on standard toxicology study. *Toxicology*. 96:225–238 (1995).

(8) Luster, M.I., Portier, C., Pait, D.G., White, K.L., Jr., Gennings, C., Munson, A.E., and Rosenthal, G.J. Risk assessment in immunotoxicology I. Sensitivity and predictability of immune tests. *Fundamental Applied Toxicology*. 18:200–210 (1992).

(9) Luster, M.I., Portier, C., Pait, D.G., Rosenthal, G.J. Germolec. D.R., Corsini, E., Blaylock, B.L., Pollock, P., Kouchi, Y., Craig, W., White, D.L., Munson, A.E., and Comment, C.E. Risk Assessment in Immunotoxicology II. Relationships Between Immune and Host Resistance Tests. *Fundamental Applied Toxicology*. 21:71–82 (1993).

(10) Temple, L., Kawabata, T. T., Munson, A. E., and White, Jr., K. L. Comparison of ELISA and plaque-forming cell assays for measuring the humoral immune response to SRBC in rats and mice treated with benzo[a]pyrene or cyclophosphamide. *Fundamental Applied Toxicology*. 21:412–419 (1993).

(11) Temple, L., Butterworth, L., Kawabata, T.T., Munson, A.E., and White, Jr., K.L. Eds. Burleson, G.R., Dean, J.H., and Munson, A.E. ELISA to Measure SRBC Specific Serum IgM: Method and Data Evaluation. Vol. 1. *Methods in Immunotoxicology* (Wiley-Liss, Inc., New York, 1995) pp. 137–157. [FR Doc. 97–21413 Filed 8–14–97; 8:45 am]

BILLING CODE 6560–50–F

Final Rule

Friday
August 15, 1997

Part IV

Department of Commerce

National Oceanic and Atmospheric
Administration

50 CFR Part 679

Fisheries of the Exclusive Economic
Zone Off Alaska; License Limitation
Program; Community Development Quota
Program; Proposed Rule

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 970703166-7166-01; I.D. 060997A]

RIN 0648-AH65

Fisheries of the Exclusive Economic Zone Off Alaska; License Limitation Program; Community Development Quota Program

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS issues a proposed rule that would implement Amendment 39 to the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (BSAI), Amendment 41 to the Fishery Management Plan for Groundfish of the Gulf of Alaska (GOA), and Amendment 5 to the Fishery Management Plan for the Commercial King and Tanner Crab Fisheries in the Bering Sea/Aleutian Islands (BS/AI). These amendments submitted by the North Pacific Fishery Management Council (Council) would establish a License Limitation Program (LLP) and expand the Community Development Quota (CDQ) Program. The LLP would limit the number, size, and specific operation of vessels that may be used in fisheries for groundfish, other than demersal shelf rockfish east of 140° W. long. and sablefish managed under the Individual Fishing Quota (IFQ) program for Pacific halibut and sablefish, in the exclusive economic zone (EEZ) off Alaska. The LLP also would limit the number, size, and specific operation of vessels that may be used in fisheries for crab species managed pursuant to the Fishery Management Plan (FMP) for Commercial King and Tanner Crab Fisheries of BS/AI. The CDQ program would be expanded by including in CDQ allocations a percentage of the total allowable catch (TAC) of groundfish in the BSAI and crab species in the BS/AI that is not currently included in the existing CDQ programs for pollock, halibut, and sablefish.

DATES: Comments must be received by September 29, 1997.

ADDRESSES: Comments must be sent to Chief, Fisheries Management Division, Alaska Region, NMFS, 709 West 9th Street, Room 453, Juneau, AK 99801, or

P.O. Box 21668, Juneau, AK 99802, Attention: Lori J. Gravel. Copies of the Environmental Assessment/Regulatory Impact Review (EA/RIR) for this action may be obtained from the above address.

FOR FURTHER INFORMATION CONTACT: John Lepore, 907-586-7228.

SUPPLEMENTARY INFORMATION: The U.S. groundfish fisheries of the GOA and the BSAI in the EEZ are managed by NMFS pursuant to the FMPs for groundfish in the respective management areas. The commercial king crab and Tanner crab fisheries in the BS/AI are managed by the State of Alaska with Federal oversight, pursuant to the FMP for those fisheries. The FMPs were prepared by the Council, pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), 16 U.S.C. 1801, *et seq.*, and are implemented by regulations for U.S. fisheries at 50 CFR part 679. General regulations at 50 CFR part 600 also apply.

License Limitation Program—Background Information

The LLP is the first stage in fulfilling the Council's commitment to develop a comprehensive and rational management program for the fisheries in and off Alaska. The Council first considered the comprehensive rationalization plan (CRP) at its meeting in November 1992. Experts on limited-entry programs were invited to testify at that meeting, and the Council reviewed initial CRP proposals from the fishing industry. In December 1992, the Council approved a problem statement describing the need for and purpose of the CRP.

The problem statement articulated the Council's concern that the domestic harvesting fleet had expanded beyond the size necessary to harvest efficiently the optimum yield (OY) of the fisheries within the EEZ off Alaska. Further, it confirmed the Council's commitment to the long-term health and productivity of the fisheries and other living marine resources in the North Pacific and Bering Sea ecosystem. To fulfill that commitment, the Council intended to design a program that would efficiently manage the resources under its authority, reduce bycatch, minimize waste, and improve utilization so that the maximum benefit of these resources would be provided to present and future generations of fishermen, associated fishing industry sectors, fishing communities, consumers, and the Nation as a whole. The Council also committed itself to support the stability, economic well-being, and diversity of

the seafood industry and provide for the economic and social needs of communities dependent on that industry.

The problem statement also contained the following 14 issues identified by the Council as areas to be addressed by the CRP:

(1) Harvesting capacity in excess of that required to harvest the resource.

(2) Allocation and preemption conflicts between and within industry sectors, such as with inshore and offshore components.

(3) Preemption conflicts between gear types.

(4) Gear conflicts within fisheries where overcrowding of fishing gear exists due to excessive participation and surplus fishing effort on limited grounds.

(5) Dead-loss such as "ghost fishing" by lost or discarded gear.

(6) Bycatch loss of groundfish, crab, herring, salmon, and other non-target species, including bycatch that is not landed for regulatory reasons.

(7) Economic loss and waste associated with discard mortality of target species harvested but not retained for economic reasons.

(8) Concerns regarding vessel and crew safety that are often compromised in the race for fish.

(9) Economic instability within various sectors of the fishing industry, and in fishing communities caused by short and unpredictable fishing seasons, or preemption that denies access to fisheries resources.

(10) Inability to provide for a long-term stable fisheries-based economy in small economically disadvantaged adjacent coastal communities.

(11) Reduction in ability to provide a quality product to consumers at a competitive price, and thus maintain the competitiveness of seafood products from the EEZ off Alaska on the world market.

(12) Possible impacts on marine mammals and seabirds, and marine habitat.

(13) Inability to achieve long-term sustainable economic benefits to the Nation.

(14) A complex enforcement regimen for fishermen and management alike that inhibits the achievement of the Council's comprehensive goal.

At its meeting in January 1993, the Council began evaluating the effectiveness of different alternatives to determine which ones would best meet the objectives of the CRP. These alternatives included: (1) Exclusive area registration; (2) seasonal allocations; (3) license limitation; (4) gear allocations; (5) inshore/offshore allocations; (6) CDQ

allocations; (7) trip limits; (8) IFQ for prohibited species catch; (9) non-transferable IFQ; (10) transferable IFQ; and (11) harvest privilege auctions. All the alternatives had qualities that would have helped achieve some of the objectives of the CRP; however, after comparing the strengths and weaknesses of the alternatives, the Council identified license limitation and transferable IFQ as the most viable alternatives.

Although transferable IFQ was identified as the alternative with the greatest potential for solving the most issues in the problem statement for the CRP, several problems prevented the Council from choosing this alternative as the first step in the CRP process. For example, determinations about who should be found eligible to receive an initial allocation of quota or how much initial quota should be issued to each eligible applicant would have been exceedingly difficult. Also, the IFQ program for halibut and sablefish had not yet been implemented; therefore, any information or experience that would have been gained from the operation of that program was not then available. For these reasons, the Council, at its meeting in September 1993, raised LLP to equal consideration with transferable IFQ as a management regime designed to meet the objectives of the CRP.

In January 1994, the Council adopted its Advisory Panel's recommendations to expedite the LLP alternative. This decision was made because the industry lacked a consensus on the specific form of a transferable IFQ alternative and a concern about the amount of time that would be necessary to produce an analysis and implement a transferable IFQ program. The transferable IFQ alternative was not dropped completely; rather, it was considered by the Council as a potential second step in the overall CRP process. Advocates for the LLP argued that it was a necessary first step in the CRP process, because it could be implemented more expeditiously and it would provide stability in the fishing industry while a transferable IFQ system was analyzed and implemented.

At its meeting in April 1994, the Council received an LLP/IFQ proposal from its State of Alaska representative. This proposal contained an integrated, step-wise approach consisting of an LLP followed by an IFQ program. This proposal became the basis for subsequent Council actions that culminated in June 1995 with the Council's adoption of the LLP which, if approved by NMFS, would be implemented by this proposed rule.

By providing stability in the fishing industry and by identifying the field of participants in the groundfish and crab fisheries, the Council recommended the LLP as an interim step toward a more comprehensive solution to the conservation and management problems of an open access fishery. Although the LLP is an interim step, it addresses some of the important issues in the problem statement developed for the CRP. The LLP, through the limits it places on the number of vessels that could be deployed in the affected fisheries, would place an upper limit on the amount of capitalization that could occur in those fisheries. This upper limit would prevent overcapitalization in those fisheries at levels that could occur in the future if such a constraint were not present.

License Limitation Program—Operational Aspects

1. General

The LLP would limit access to the commercial groundfish fisheries in the EEZ off Alaska, except for demersal shelf rockfish east of 140° W. long. and sablefish managed under the IFQ program (license limitation groundfish). Demersal shelf rockfish east of 140° W. long. would be excluded from the LLP because an alternative management program for that species currently is under consideration. Sablefish would be excluded because that species is managed under the IFQ program. The LLP also would limit access to the commercial crab fisheries in the BS/AI, managed pursuant to the FMP for the Commercial King and Tanner Crab Fisheries in the BS/AI.

2. Nature of Licenses and Qualification Periods

Licenses for license limitation groundfish would be issued to eligible applicants based on fishing that occurred from an eligible applicant's qualifying vessel in management areas (i.e., BSAI, GOA, or BSAI/GOA, or state waters shoreward of those management areas) during the general qualification period (GQP), and in endorsement areas defined by these regulations (i.e., Aleutian Islands, Bering Sea, Central Gulf, Southeast Outside, and Western Gulf, or state waters shoreward of those endorsement areas) during the endorsement qualification period (EQP). These licenses would authorize holders to conduct directed fishing for license limitation groundfish species in the endorsement areas designated on each license and would be transferrable. The GQP for license limitation groundfish would be January 1, 1988, through June

27, 1992, except for vessels under 60 ft (18.3 m) which made a legal landing of license limitation groundfish with pot or jig gear prior to January 1, 1995. For those vessels, the GQP would be extended through December 31, 1994. The Council recommended this extension so that vessels that entered the fishery after June 27, 1992, but that used gear that minimized bycatch loss and waste due to discard mortality, could be used for qualification. Qualification under this extension would be limited to one endorsement area to ensure that capacity would not be unduly increased. Minimizing bycatch loss and waste due to discard mortality are important objectives of the CRP (see issues (6) and (7) of the problem statement above). Additionally, an eligible applicant whose qualifying vessel "crossed-over" to groundfish from crab under the provisions of the moratorium on entry by June 17, 1995, also would qualify under the GQP for license limitation groundfish.

The EQP for license limitation groundfish would be January 1, 1992, through June 17, 1995. The area endorsement(s) designated on a groundfish license would authorize the holder to conduct directed fishing in the following areas: (1) Bering Sea Subarea; (2) Aleutian Islands Subarea; (3) Western Area of the Gulf of Alaska; (4) Central Area of the Gulf of Alaska and the West Yakutat District; and (5) Southeast Outside District.

The Council designed the dual qualification periods (i.e., the GQP and the EQP) to account for past and recent participation in the affected fisheries. The GQP, which includes the qualification period for the moratorium on entry, would account for past fishing participation, and the EQP would account for the recent fishing participation that occurred up to the Council's final action on the LLP (June 17, 1995). The Council felt that it was critical that a qualifying vessel have fishing history in both periods, thereby showing past dependence and recent participation, to qualify its owner on June 17, 1995, for a license. The Council recommended dual qualification periods for crab species licenses for the same reason.

Licenses for crab species would be issued to eligible applicants based on fishing that occurred from the qualifying vessel in the BS/AI during the GQP, and for a specific species in an endorsement area (i.e., Adak brown king, Adak red king, Bristol Bay red king, *C. opilio* and *C. bairdi*, Dutch Harbor brown king, Norton Sound red king and Norton Sound blue king, Pribilof red king and Pribilof blue king, and St. Matthew blue

king) during the EQP. These licenses would authorize holders to conduct directed fishing for specific crab species in Federal waters of the specific areas designated on each license and would be transferrable. The GQP for crab species would be January 1, 1988, through June 27, 1992. Vessels that participated in the Norton Sound king crab fisheries and the Pribilof king crab fisheries would be exempt from the landing requirements of the GQP because: (1) The Norton Sound king crab fisheries began to be managed by the State of Alaska under a system of super-exclusive registration in 1993, and (2) the Pribilof king crab fisheries were closed from 1988 through 1992. Eligibility for those fisheries would be based exclusively on participation during a separate EQP. Additionally, an eligible applicant whose qualifying vessel "crossed-over" to crab from groundfish under the provisions of the moratorium on entry by December 31, 1994, also would qualify under the GQP for crab species.

The EQP for crab species would vary among eight area/species endorsements. The EQP for (1) Pribilof red and Pribilof blue king and (2) Norton Sound red and Norton Sound blue king would be January 1, 1993, through December 31, 1994. The EQP for (3) *C. opilio* and *C. bairdi* (Tanner crab), (4) St. Matthew blue king, (5) Adak brown king, (6) Adak red king, and (7) Dutch Harbor brown king would be January 1, 1992, through December 31, 1994. The EQP for (8) Bristol Bay red king would be January 1, 1991, through December 31, 1994. These endorsement periods were designed to accommodate the different patterns of season openings and closures for specific crab species. For example, the Bristol Bay red king crab fishery was not open in 1994; therefore, a 3-year participation window is provided by using a January 1, 1991, start date. The variations in the EQP for the Norton Sound king crab fisheries and the Pribilof king crab fisheries are explained in the GQP discussion above.

3. License Designations and Vessel Length Categories

All licenses for license limitation groundfish and crab species would be designated for use by either catcher vessels or catcher/processor vessels. This designation would prescribe the authorized behavior of the license holder on the vessel on which the license would be used. A catcher vessel designation on a groundfish license would authorize a license holder to conduct directed fishing for license limitation groundfish species and a catcher designation on a crab species

license would authorize a license holder to conduct directed fishing for crab species. A license with a catcher vessel designation would not authorize a license holder to process license limitation groundfish or crab species. A catcher/processor vessel designation on a groundfish license would authorize a license holder to conduct directed fishing for, and process, license limitation groundfish. Similarly, a catcher/processor designation on a crab species license would authorize a license holder to conduct directed fishing for, and process, crab species. A license with a catcher/processor designation also would authorize a license holder to conduct directed fishing for but not process license limitation groundfish or crab species (i.e., the license holder is not required to process his or her catch).

The Council also provided that persons could change the vessel designation on their licenses from a catcher/processor to a catcher vessel. This change in designation would be permanent; that is, once a vessel designation was changed from a catcher/processor vessel to a catcher vessel, the license holder would no longer be able to process license limitation groundfish or crab species using that license.

The length overall (LOA) of a vessel is defined at § 679.2 as the horizontal distance between the foremost part of the stem and the aftermost part of the stern, excluding bowsprits, rudders, outboard motor brackets, and similar fittings or attachments, measured in linear feet and rounded to the nearest foot. The size categories were selected in order to be consistent with size categories in other programs; in addition, some observer requirements vary with vessel size, and these categories are consistent with those observer requirements. The following convention would be used when rounding the LOA to the nearest foot.

(1) When the amount exceeding a whole foot measurement is less than 6 inches (15.2 cm), the LOA would be equal to that whole foot measurement. For example, if the horizontal distance of a vessel is 124 ft, 5¾ inches (37.9 m), the LOA of the vessel would be 124 ft (37.8 m).

(2) When the amount exceeding a whole foot measurement is greater than 6 inches (15.2 cm), the LOA would be equal to the next whole foot measurement. For example, if the horizontal distance of a vessel is 124 ft, 6½ inches (38.0 m), the LOA of the vessel would be 125 ft (38.1 m).

(3) When the amount exceeding a whole foot measurement is exactly 6

inches (15.2 cm), the LOA would be equal to that whole foot measurement if the number is even; however, if the number is odd, the LOA would be equal to the next whole foot measurement. For example, if the horizontal distance of a vessel is 124 ft, 6 inches (37.9 m), the LOA of the vessel would be 124 ft (37.8 m), but, if the horizontal distance of the vessel is 59 ft, 6 inches (18.1 m), the LOA of the vessel would be 60 ft (18.3 m).

All licenses for license limitation groundfish and crab species would be issued with a specific vessel length category designated on the license. These categories are: (1) Category "A", which is comprised of vessels with an LOA of 125 ft (37.8 m) or greater; (2) category "B", which is comprised of vessels with an LOA from 60 ft (18.3 m) to 124 ft (37.5 m); and (3) category "C", which are vessels with an LOA of 59 ft (18 m) or less. A license would be issued with the appropriate specific vessel length category, based on the qualifying vessel's LOA on June 17, 1995.

Vessels participating under the moratorium on entry may be lengthened to their maximum length overall (MLOA). A vessel's MLOA would be 1.2 times its LOA on June 24, 1992, except: (1) For a vessel that was under reconstruction on June 24, 1992, its MLOA would be 1.2 times its LOA on the date reconstruction was completed; or (2) for a vessel that was 125 ft (37.8 m) or greater and that was under reconstruction on June 24, 1992, its MLOA would be its LOA on June 24, 1992, or its LOA on the date reconstruction was completed.

The vessel lengthening provisions of the moratorium on entry explained above provide some permissible flexibility to lengthen a vessel under the LLP. Specifically, a vessel may be lengthened to its MLOA under the moratorium on entry provided it was lengthened before June 17, 1995, or, if not, provided the lengthening does not cause the vessel to exceed the vessel's length category under the LLP. For example, a vessel that was 58 ft (17.7 m) on June 24, 1992, could be lengthened to 70 ft (21.4 m) under the provisions of the moratorium on entry. If the vessel had been lengthened before June 17, 1995, then the license issued would have a category "B" vessel length designation, which could be used on a vessel with an LOA from 60 ft (18.3 m) to 124 ft (37.5 m). However, if the vessel had been lengthened after June 17, 1995, then the license issued would have a category "C" vessel length designation (based on its LOA on June 17, 1995), which could be used on a vessel with

an LOA of 59 ft (18 m) or less. Therefore, although vessels may be lengthened under the provisions of the moratorium on entry, vessels may not be lengthened after June 17, 1995, beyond their length categories and still be eligible for LLP fishing with the license issued based on that vessel's LOA on June 17, 1995. For vessels that were lengthened under the provisions in the moratorium on entry, NMFS will require evidence of the date the vessel was lengthened, and the LOA of the vessel before and after that date. In addition, NMFS will require evidence of the vessel's LOA on June 17, 1995. In such circumstances, evidence bearing upon the vessel's LOA on the relevant dates could consist of a past marine survey, an original builder's certificate and any admeasurement documents submitted to the U.S. Coast Guard National Vessel Documentation Center, a certificate of registration that states the vessel's length, or other credible evidence. For the convenience of initial issues and future transferees, LLP licenses issued for a vessel will state its MLOA.

Difficulties have been reported with at-sea monitoring for compliance with vessel length categories based on the current definition of LOA at § 679.2. In order to obtain an accurate measurement of LOA, a vessel must be moored to a wharf or dock upon which the distance between the foremost part of the stem and the aftermost part of the stern can be carefully marked and measured. Such careful marking and measurement is not possible while the vessel is at sea. Consequently, at-sea enforcement of fishery regulations incorporating the LOA definition is impaired. Moreover, vessel owners and operators could be inconvenienced in some situations while enforcement officers arrange to have a vessel's LOA measured in port.

For these reasons, NMFS specifically requests public comments on alternative methods of determining or verifying LOA while a vessel is at sea. In particular, NMFS requests comments on the efficacy of redefining LOA as follows: for a vessel documented by the U.S. Coast Guard, the Coast Guard documented length; for an undocumented vessel that has been issued a certificate of registration, the length that appears on the vessel's certificate of registration; and for a vessel that is neither documented nor registered, the length as determined by the current definition of LOA at § 679.2. If the LLP portions of the amendments are approved, the final rule may make these or other changes to the definition of LOA depending in large part upon

the comments received during the public comment period.

4. Landing Requirements

The landings that owners of vessels would need to qualify for a particular area endorsement for a groundfish license would vary according to vessel length category, the area, and vessel designation. These differing requirements are intended by the Council to account for differences in the operational characteristics of the fisheries, differences in the geographical areas in which the fisheries are prosecuted, and differences in the social and economic conditions that affect participants in the fisheries from various coastal areas. For instance, the dependence of fishing communities around the Gulf of Alaska on small vessel fleets would be accounted for by requiring only a single landing during the appropriate time periods for vessels less than 60 ft (18.3 m) LOA to qualify for an endorsement. The single landing requirement would be extended to catcher vessels less than 125 ft (37.8 m) LOA in the Western Gulf because public testimony during Council consideration of the LLP indicated that local fleets did not participate in that area during the earlier portion of the EQP. Consequently, the Council concluded that excluding those fleets from adjacent fishing grounds through more stringent landing requirements would significantly harm local communities dependent on those fisheries. Catcher/processor vessels in the Western Gulf area that were 60 ft (18.3 m) to less than 125 ft (37.8 m) LOA, would have the same landing requirements as all vessels of similar length in the Central Gulf area and Southeast Outside district because of their fishing capacity. Also, based on information in the LLP analysis that multiple landing requirements in the Bering Sea subarea and Aleutian Islands subarea would unduly burden small vessels, but would not affect larger vessels, which contributed to the largest portion of capacity in the fleet in those areas, the Council determined that a single landing requirement would best reflect the operational characteristics of the fisheries in those areas. Finally, the Council received public testimony during consideration of the LLP that some vessels that qualified under the moratorium on entry entered into the fishery during the latter portion of the EQP. The Council recommended that a four-landing provision be added to the EQP landing requirements in certain areas to account for participation of these vessels. The Council felt that four landings would be sufficient to show that a person intended to remain in the

fishery and that his or her participation was not merely speculative and opportunistic. Based on these considerations, the Council recommended the following landing requirements:

For vessels in all three length categories ("A," "B," and "C"), one landing of a license limitation groundfish species harvested in the appropriate area during the EQP to qualify their owner(s) for an Aleutian Islands area endorsement or a Bering Sea area endorsement; for vessels in length category C, one landing of license limitation groundfish species harvested in the appropriate area during the EQP to qualify their owner(s) for a Western Gulf area endorsement, a Central Gulf area endorsement, and a Southeast Outside area endorsement; for vessels in length category B designated as catcher vessels, one landing of license limitation groundfish species harvested in the appropriate area during the EQP to qualify their owner(s) for a Western Gulf area endorsement. Vessel length category "B" vessels would require one landing of license limitation groundfish species harvested in the appropriate area in each of any 2 calendar years from January 1, 1992, through June 17, 1995, or four landings of license limitation groundfish species harvested in the appropriate area between January 1, 1995, through June 17, 1995, for a Central Gulf area endorsement or a Southeast Outside area endorsement. This landing requirement also would apply to vessels designated as catcher/processor vessels and in vessel length category "B" for a Western Gulf area endorsement. Vessel length category "A" vessels would require one landing of license limitation groundfish species harvested in the appropriate area in each of any 2 calendar years from January 1, 1992, through June 17, 1995, for a Central Gulf area endorsement, a Southeast Outside area endorsement, and a Western Gulf area endorsement.

The landings owners of vessels would need to qualify for a particular area/species endorsement for a crab species license would vary according to the crab species. The Council recommended differing requirements to ensure that incidental catches would not qualify a person for a license (e.g., incidentally caught Tanner crab with red or blue king) but allow for participation in some fisheries where a single landing may have indicated that a person intended to remain in a fishery (e.g., the Pribilof red and blue king crab fishery that was closed from 1988 through 1992). The following requirements were recommended by the Council: For a red and blue king crab license, one landing

of the appropriate crab species harvested in the appropriate fishery during the EQP; for a brown king and Tanner crab license, three landings of the appropriate crab species harvested in the appropriate fishery during the EQP.

The appropriate fishery is the area, as defined in the proposed regulations, that corresponds to the area/species endorsement for which the person is seeking qualification. Only legal landings would qualify. As defined in the proposed regulations, a legal landing is a landing in compliance with Federal and state commercial fishing regulations in effect at the time of landing.

5. License Recipients

Licenses would be issued to eligible applicants. Eligible applicants must have been eligible, on June 17, 1995 (the date of final Council action on the LLP), to document a fishing vessel under Chapter 121 of Title 46, U.S.C. An eligible applicant would be the owner, on June 17, 1995, of a qualified vessel or, if the fishing history of that qualified vessel has been transferred to another person by the express terms of a written contract that clearly and unambiguously provides that the qualification for a license under the LLP has been transferred, the person to which the qualification was transferred by the express terms of a written contract. The Council recommended that NMFS recognize written contracts to the extent practicable; however, in the event of a dispute concerning the disposition of the license qualification by written contract, NMFS would not issue a license until the dispute was resolved by the parties involved. For determining the qualification for a license in the absence of a written contract the Council recommended the following: (1) If the vessel were sold on or before June 17, 1995, the vessel's fishing history and license qualification transfers with the vessel; (2) if the vessel were sold after June 17, 1995, the vessel's fishing history and license qualification remain with the seller; (3) only one license be issued based on the landings of any qualified vessel. For instance, a vessel's fishing history could not be divided so that multiple licenses could be issued based on separate qualifications created by that division. Also, if there had been multiple owners of a qualified vessel on June 17, 1995, then one license would be issued in the name of the multiple owners. A qualified vessel is one from which legal landings were made during the appropriate qualifying periods in § 679.4(i) (4) and (5) of this proposed rule.

A successor-in-interest would be eligible to apply for a license in the place of eligible applicant if the eligible applicant, because of death or dissolution, could not apply for the license.

NMFS will assemble a comprehensive database containing relevant data on landings, vessels, and ownership. That database will be the "Official Record" regarding eligibility for a license. Persons that appear to be eligible, premised on the information contained in the Official Record, would be notified of their status and invited to request an application from NMFS. Other persons, who may not initially appear eligible to NMFS, could also request an application from NMFS. On receipt of the request for application, NMFS would prepare an application premised on information in the Official Record and send it to the applicant. Applicants would then have an opportunity to review the information provided, make changes if appropriate, and return the completed application to NMFS. No license would be issued unless the application were returned to NMFS, and NMFS determined the applicant to be eligible for a license.

Applicants who disagreed with the information in the Official Record (i.e., applicants who contended that the information was incomplete or incorrect, or both) would have an opportunity to demonstrate the validity of their contentions. For example, if the official record did not contain records of landings for a vessel during the GQP, a person could provide State of Alaska fish tickets to demonstrate those landings. Similarly, if an application were submitted based on a claim of unavoidable circumstances, the person submitting the application would need to provide sufficient evidence to verify the claim. Further information on the requirements for a claim of unavoidable circumstances is provided in Section 8, Other Provisions, below.

Applicants would be notified of the disposition of their applications (i.e., whether the application was approved, partially approved, or disapproved). If the application were approved, then a license would be issued to the applicant. If the application were partially approved, or disapproved, the applicant would be provided an opportunity to submit evidence to support any claim that NMFS could not verify. Evidence submitted in a timely matter would be reviewed and used as the basis for reconsideration. NMFS' initial determination on an application would stand if an applicant fails to submit corroborating evidence within the time period provided.

The disapproval of an application would be an initial administrative determination that could be appealed under 50 CFR 679.43. For applications for which NMFS considers additional evidence to support previously unsupported claims, NMFS's determination on the validity of the claims would be an initial administrative determination that could be appealed.

If an appeal were filed and accepted, the applicant would receive a non-transferable license authorizing that person to conduct directed fishing for license limitation groundfish or crab species based on any approved portion of the application. Further, the non-transferable license would [could also] authorize directed fishing for license limitation groundfish or crab species based upon the denied claims accepted for appeal, until the appeal was resolved. If an applicant's appeal were denied, then that applicant would only receive a license to conduct directed fishing for license limitation groundfish or crab species based on the approved portion of the application.

6. Transfer and Reissuance of Licenses

A license holder may request NMFS, on a form available from NMFS, to transfer the license to a recipient designated by the license holder on the request form. The designated recipient may not conduct directed fishing for license limitation groundfish or crab species until NMFS reissues the license in the name of the recipient. NMFS will not reissue a license unless the license holder submits a completed, signed, and dated request form to NMFS and NMFS determines that the designated recipient is a person able to document a fishing vessel under Chapter 121, Title 46, U.S.C., that no party to the transfer has any fines, civil penalties, other payments due and outstanding, or outstanding permit sanctions resulting from Federal fishing violations involving any party to the transfer, and that the transfer will not cause the recipient to exceed the license caps in proposed § 679.7(i).

When reissued, the recipient may use the license for any vessel designation and vessel length category originally assigned to the license, or on any vessel equal to, or shorter than, the MLOA set forth on the license, regardless of vessel length category. For example, a license with a MLOA of 145 ft (44.2 m) could be used on a vessel 145 ft (44.2 m) or shorter, regardless of whether the vessel is in category "A", "B", or "C", as long as the vessel conforms with all other requirements, such as vessel designation and area endorsement. The Council

included this provision to allow for increased transfer flexibility.

7. License Severability and Ownership Caps

Area endorsements for groundfish licenses or area/species endorsements for crab species licenses would not be severable from the license. For example, a person transferring a groundfish license with a Southeast Outside area endorsement and a Central Gulf area endorsement would necessarily transfer both area endorsements with the license and could not keep one area endorsement while transferring the other. Similarly, vessel designations and vessel length categories would not be severable from the license. The non-severability of licenses was recommended by the Council to prevent increased capacity in the affected fisheries.

Also, for at least 3 years after implementation, a groundfish license and crab species license initially issued to a person would not be severable if those licenses resulted from the landings of the same qualifying vessel. The Council intends to review the issue of severability 3 years after implementation of the LLP. After that review, if the Council decides that the reason for non-severability (i.e., excess effort in the fisheries) has been ameliorated, then the Council may remove the prohibition on severing initially issued groundfish and crab species licenses. Groundfish licenses and crab species licenses obtained by transfer could not be combined with any other licenses held by a person and would remain separate licenses.

A person would be limited to a maximum of ten groundfish licenses and five crab species licenses, unless that person is initially issued more than those numbers of licenses, in which case the person could hold more licenses than specified by the license limit. However, a person above the limit could not receive a new groundfish license or a crab species license by transfer until the number of licenses held by that person is below the maximum number for the respective limits. After obtaining transfer eligibility by dropping below the license limit, a person could not exceed that limit, notwithstanding the earlier status of being allowed to exceed that limit on initial issuance. These limits were recommended by the Council to prevent any person from obtaining an excessive share of harvest privileges in the affected fisheries.

8. Other Provisions

The Council included several other provisions in the proposed LLP. First, the Council recommended that persons targeting species not included in the groundfish portion of the LLP and who are currently allowed to land incidentally taken license limitation groundfish species be authorized under the LLP to continue landing bycatch amounts of license limitation groundfish species without a groundfish license. This provision is intended to avoid the waste that occurs when bycatch is required to be discarded. This is especially true for programs like the IFQ program for sablefish and halibut, where the targeted species and license limitation groundfish species may be found in the same habitat area.

Second, the Council recommended that the owner of a vessel who qualifies for a license under the LLP but whose vessel was lost or destroyed be eligible for the license and accompanying endorsements, designation, and vessel length category. This license could not be used for harvesting applicable species unless the vessel on which the license is used conforms with all the requirements of the LLP.

Third, the Council recommended that an "unavoidable circumstances" provision be included in the LLP. This provision would allow the owner of a vessel on June 17, 1995, to receive a license, even though the vessel on which the application would be based did not meet all of the landing requirements necessary to qualify that owner for a license. That owner, hereafter applicant, would need to provide evidence during the application process that the vessel made a legal landing of license limitation groundfish species, or crab species if applicable, between January 1, 1988, and February 9, 1992. The applicant would also need to provide evidence that, due to factors beyond the control of the owner of the vessel at that time, the vessel was subsequently lost, damaged, or unable to qualify the applicant for a license under the criteria in § 679.4(i) (4) or (5). Furthermore, the applicant must demonstrate:

(1) That the owner of the vessel at that time held a specific intent to conduct directed fishing for license limitation groundfish (crab species) with that vessel during a specific time period in a specific area.

(2) That the specific intent to conduct directed fishing for license limitation groundfish (crab species) with that vessel was thwarted by a circumstance that was:

(a) Unavoidable.

(b) Unique to the owner of that vessel, or unique to that vessel.

(c) Unforeseen and reasonably unforeseeable to the owner of the vessel.

(3) That the circumstance that prevented the owner from conducting directed fishing for license limitation groundfish (crab species) actually occurred.

(4) That, under the circumstances, the owner of the vessel took all reasonable steps to overcome the circumstance that prevented the owner from conducting directed fishing for license limitation groundfish (crab species).

(5) That license limitation groundfish (appropriate crab species) were harvested on the vessel in the specific area that corresponds to the area endorsement (area/species endorsement) for which the claimant is applying and the harvested license limitation groundfish (crab) was legally landed after the vessel was prevented from participating by the unavoidable circumstance but before June 17, 1995.

If all these criteria are met to the satisfaction of NMFS, a license may be issued for the appropriate fishery and endorsement area. This provision is not designed to be a "loop hole" through which owners of vessels that have not met the qualification requirements could be issued licenses. If an applicant failed to demonstrate that an unavoidable circumstance prevented the vessel from meeting the qualifications in § 679.4(i) (4) or (5), NMFS would not issue a license.

Fourth, the Council recommended that licenses be issued to owners of vessels that made a legal landing of license limitation groundfish species harvested during the GQP in one management area and a legal landing of license limitation groundfish species harvested during the EQP in another management area. For example, suppose a vessel in length category "C" made only two legal landings of license limitation groundfish species. The first legal landing was of license limitation groundfish species harvested in the BSAI on December 31, 1991, and the second legal landing was of license limitation groundfish species harvested in the Central Gulf endorsement area on June 16, 1995. Although the owner of the vessel would not qualify for a license under the standard eligibility criteria (i.e., making a landing during the GQP and the EQP of license limitation groundfish species harvested in the same management area), this owner would qualify for a license under the alternative method of eligibility. Section 679.4(i)(4) (iv) and (v) provide that if a vessel makes a legal landing during the GQP (and not the EQP) of

license limitation groundfish species harvested in one management area and a legal landing during the EQP (and not the GQP) of license limitation groundfish species harvested in another management area, then the owner of the vessel would qualify for a license for the management area in which the vessel harvested license limitation groundfish species during the EQP. The owner of the vessel in the example above would receive a license for the Gulf of Alaska with a Central Gulf area endorsement.

Fifth, the Council recommended a no-trawl zone east of 140° W. long. (Southeast Outside District). Owners of vessels that qualify for a groundfish license for the Gulf of Alaska with a Southeast Outside area endorsement would not be able to use trawl gear in that area regardless of whether trawl gear were used to harvest license limitation groundfish species during the EQP. The proposed no-trawl zone is designed to prevent preemption conflicts between gear types, prevent fixed gear loss, and to provide for the socio-economic needs of communities dependent on the local fisheries in the Southeast Outside District.

Three types of preemption can occur among competing gear types. Direct preemption occurs when competing gear types target the same species. Rockfish species such as rougheye, other slope, and thornyhead rockfish are examples of species that would be targeted by trawl gear and fixed gear fisheries in the Southeast Outside District. Establishing a no-trawl zone would eliminate direct preemption by trawl gear. Indirect preemption occurs when one gear type impacts or precludes a target fishery by another gear type by incidentally catching the target species. Incidental catches of species made by trawl gear could preclude fixed gear target fisheries that are critical to the socio-economic viability of small communities in Southeast Alaska. Indirect preemption by trawl gear also would be eliminated by restricting the Southeast Outside Regulatory District to fixed gear only. Grounds preemption occurs when the operator of a vessel using one type of fishing gear chooses not to fish in an area because of the gear type being used by the operator of another vessel in the same area. For example, an operator of a vessel using longline gear may be hesitant to deploy gear in an area in which trawl gear will be used because of the possibility of the longline gear being lost or damaged by the trawl gear. This third type of preemption also would be eliminated by the establishment of a no-trawl zone. Fixed gear loss occurs when trawl gear is

towed over a fixed gear set. This loss can lead to higher fishing mortality due to "ghost fishing" (i.e., fishing that occurs when fish are caught on unretrieved gear).

Western Alaska Community Development Quota Program

Background Information

The goals and purpose of the CDQ program are to allocate CDQ to eligible Western Alaska communities to provide the means for starting or supporting commercial fishery activities that will result in ongoing, regionally based, commercial fishery or related businesses. The CDQ program began in 1992 with the pollock CDQ fishery, which was developed by the Council as part of Amendment 18 to the BSAI FMP. The approved portion of Amendment 18 and the final rule implementing Amendment 18 (57 FR 23321, June 3, 1992) allocated pollock for the CDQ program only for a temporary period from 1992 through 1995. The amendment allocated to a pollock CDQ reserve, one-half of the 15 percent of the pollock TAC that is placed in the non-specific reserve for each subarea or district of the BSAI.

Eligible CDQ communities could apply for a CDQ allocation from the CDQ reserve by submitting a Community Development Plan (CDP). Regulations implementing the CDQ program for 1992 and 1993 (57 FR 54936, November 23, 1992) specified the process for applying for the CDQ program and the required contents of CDPs. A subsequent regulatory amendment (58 FR 32874, June 14, 1993) implemented the CDQ program for 1994 and 1995.

The Council recommended reauthorizing the pollock CDQ program for an additional 3 years as part of Amendment 38 to the BSAI FMP, and NMFS approved this amendment on November 28, 1995. Regulations implementing the pollock CDQ program for 1996 through 1998 were published on December 12, 1995 (60 FR 63654, corrected 61 FR 20, January 2, 1996).

The Council recommended adding the halibut and fixed gear sablefish (H/S) fisheries to the CDQ program beginning in 1995, as part of the IFQ program. The final rule implementing the IFQ program (58 FR 59375, November 9, 1993) implemented the H/S CDQ program with no expiration date. More background and explanation of the pollock and H/S CDQ programs can be found in the preambles to the above final rules.

Regulations implementing the pollock CDQ program were codified at 50 CFR

part 675, and regulations implementing the H/S CDQ program were codified at 50 CFR part 676. NMFS subsequently consolidated both sets of CDQ regulations into one set of regulations at 50 CFR part 679, subpart C (61 FR 31228, June 19, 1996).

At its meeting in June 1995, the Council recommended a further expansion of the CDQ program. The Council recommended that 7.5 percent of all BSAI groundfish TACs not already covered by a CDQ program along with a pro-rata share of the prohibited species catch (PSC) limit, and 7.5 percent of the BS/AI crab be allocated to CDQ communities as defined in the regulations implementing the current CDQ program. The Council recommended that the expanded program be designed similarly to the current pollock CDQ program. Further, the Council did not recommend a termination date as currently exists for the pollock CDQ program.

Based on the Council's recommendation to expand the CDQ program to include groundfish in the BSAI and crab in the BS/AI, NMFS prepared a CDQ Program Design. The CDQ Program Design was an outline for implementing the groundfish and crab CDQ programs and for combining them with the existing pollock and H/S CDQ programs. NMFS submitted the CDQ Program Design to the Council for review at its meeting in April 1996 and requested clarification on several CDQ policy issues. This proposed rule is based on that CDQ Program Design and the clarification provided by the Council.

Expectations for Monitoring the CDQ Fisheries

The level of accountability for catch under the multispecies CDQ program determines the complexity of the monitoring program and the resulting cost to the CDQ groups, their industry partners, and the public. This proposed rule is based on NMFS' description and the Council's approval of a CDQ program design in which individual CDQ groups would be eligible to receive allocations of all groundfish TAC species or species groups, and prohibited species to support their groundfish, halibut, and crab CDQ.

Under the proposed multispecies CDQ program, NMFS would be responsible for monitoring and enforcing the groundfish and halibut CDQs. The State of Alaska (State) would be responsible for monitoring and enforcing the crab CDQs under authority contained in the FMP for the Commercial King and Tanner Crab Fisheries in the BS/AI.

In the CDQ fisheries managed by NMFS, all groundfish, prohibited species, and halibut catch and bycatch in CDQ fisheries, including the existing pollock, sablefish, and halibut CDQ fisheries, would accrue to CDQ or prohibited species quotas (PSQ) allocated to the CDQ group. Catch of groundfish or halibut in excess of a CDQ or PSQ would be prohibited under § 679.7(d)(6). Catch of the salmon, herring, and crab PSQ would result in the same time and area closures that exist for these prohibited species in the open access groundfish fisheries. Failure to account for all allocated bycatch species in the groundfish or halibut CDQ fisheries would result in the CDQ program exceeding groundfish and halibut PSQ allocations recommended by the Council. The groundfish CDQ program would not have a "prohibited species status" that would allow for continued fishing for one groundfish species once the quota of another groundfish species has been reached. No provision would be included to allow overages from the CDQ fisheries to accrue to TACs and PSC limits in the non-CDQ fisheries.

Based on this program design, the multispecies groundfish and halibut CDQ program would require a higher level of accountability than any fishery NMFS is currently managing off Alaska. The existing pollock, sablefish, and halibut CDQ fisheries and the fixed gear halibut and sablefish IFQ fisheries are target fishery-based quota programs that do not require accounting for all TAC and PSC species in the catch.

Combining Existing and Proposed CDQ Programs

NMFS proposes to combine the existing pollock and fixed gear halibut and sablefish CDQ programs with the proposed groundfish and crab CDQ programs into a single multispecies CDQ program. A combined CDQ program would simplify the CDP process, provide for full accounting of all CDQ and PSQ in the groundfish and halibut CDQ programs, apply NMFS' monitoring requirements equitably, and decrease the administrative burden on the CDQ groups, the State, and NMFS.

Under the proposed multispecies CDQ program, each CDQ group would submit one CDP for all species, and CDQ allocations for all species would be made every 3 years. Requirements for recordkeeping and reporting, observer coverage, and equipment for improved catch estimates would be applied equally to all participants in the groundfish and halibut CDQ fisheries based on vessel or processor type, not on target fishery. For example,

requirements for a longline vessel harvesting sablefish CDQ would be the same as the requirements for that vessel harvesting Pacific cod CDQ.

At its April 1996, meeting, the Council recommended that full integration of the catch monitoring and equipment requirements for the groundfish and halibut CDQ fisheries be delayed until 1999. Therefore, 1998 would be a transition year from the existing separate CDQ programs by target species to an integrated CDQ program in which all participants in the groundfish and halibut CDQ fisheries would follow the same catch monitoring and reporting requirements specified by vessel and processor type rather than by CDQ target fishery. In 1998, CDQ vessels and processors participating in the pollock and H/S CDQ programs would be exempt from the groundfish CDQ program catch monitoring regulations.

The Council's recommendation would result in four categories of CDQ fisheries in 1998 and two categories in 1999 and future years. The four categories for 1998 would be: (1) The pollock CDQ fisheries; (2) the fixed gear halibut and sablefish CDQ fisheries; (3) the groundfish CDQ fisheries, which would exclude pollock and fixed gear sablefish; and (4) the crab CDQ fisheries. The multispecies CDQ fisheries would be divided into two categories for 1999 and future years: (1) The groundfish and halibut CDQ fisheries managed by NMFS; and (2) the crab CDQ fisheries managed by the State.

Description of CDQ Species

The multispecies CDQ program would include the existing CDQ species of pollock, fixed-gear sablefish and halibut; and the proposed CDQ groundfish, crab, and PSQ species. The proposed CDQ groundfish species include all other BSAI groundfish species or species groups that have an annually specified TAC and are not part of the current CDQ program. The proposed PSQ species are defined at § 679.21(b)(1) and include any of the species of Pacific salmon (*Oncorhynchus* spp.), steelhead trout (*Oncorhynchus mykiss*), halibut, Pacific herring (*Clupea harengus pallasii*), king crab, and Tanner crab. The proposed crab CDQ species include all king and Tanner crab species in the BSAI that have a guideline harvest level (GHL) specified by the State.

CDQ Reserves, Allocations, and Quotas

The multispecies CDQ program would assign a portion of each CDQ species and PSQ species to a separate CDQ reserve. The following would be the amount assigned to each CDQ reserve

for the exclusive use of the CDQ program:

(1) *Pollock CDQ reserve*. One-half of the pollock TAC that is placed in the non-specific reserve for each subarea or district of the BSAI would be assigned to the pollock CDQ reserve.

(2) *Halibut CDQ reserve*. A separate halibut CDQ reserve would be implemented for the following International Pacific Halibut Commission (IPHC) management areas:

(A) *Area 4B*. In IPHC regulatory area 4B, 20 percent of the annual halibut quota would be made available for the halibut CDQ program to eligible communities physically located in or proximate to this regulatory area.

(B) *Area 4C*. In IPHC regulatory area 4C, 50 percent of the halibut quota would be made available for the halibut CDQ program to eligible communities physically located in this regulatory area.

(C) *Area 4D*. In IPHC regulatory area 4D, 30 percent of the halibut quota would be made available for the halibut CDQ program to eligible communities located in or proximate to IPHC regulatory areas 4D and 4E.

(D) *Area 4E*. In IPHC regulatory area 4E, 100 percent of the halibut quota would be made available for the halibut CDQ program to communities located in or proximate to this regulatory area.

(3) *Sablefish CDQ reserves*. Two sablefish CDQ reserves would be established:

(A) *Fixed gear sablefish CDQ reserve*. NMFS would assign 20 percent of the fixed gear allocation of sablefish in each subarea or district of the BSAI as a fixed-gear sablefish CDQ reserve. Sablefish in this reserve could be harvested only by vessels using fixed gear as required by the FMP amendment establishing the H/S CDQ program.

(B) *Sablefish CDQ reserve*. NMFS would assign 7.5 percent of the trawl gear allocation of sablefish in each subarea or district of the BSAI as a sablefish CDQ reserve. Sablefish in this reserve could be harvested by vessels using any authorized gear because no gear restrictions were recommended by the Council for the multispecies CDQ program.

(4) *Groundfish CDQ reserves*. NMFS would assign one-half of the amount of each groundfish TAC that is placed in the reserve for each subarea or district of the BSAI to a separate CDQ reserve for each subarea or district of the BSAI. The groundfish CDQ reserves do not include sablefish.

(5) *PSQ reserves*. NMFS would assign seven and one-half percent of each of the PSC species defined at § 679.21(b)(1) to a separate PSQ reserve.

(6) *Crab CDQ reserves.* The Council's recommendation on crab CDQs in June 1995, stated that 7.5 percent of the crab GHLS in the BS/AI would be made available to the CDQ program at the beginning of the multispecies CDQ program's implementation. However, the reauthorization of the Magnuson-Stevens Act, which became effective in October 1996, requires that the crab CDQ program be phased-in according to the following percentages: 3.5 percent for 1998, 5.0 percent for 1999, and 7.5 percent for the year 2000 and thereafter. These proposed regulations reflect the requirements of the Magnuson-Stevens Act.

A CDQ allocation is a percentage of a CDQ reserve that is assigned to a CDQ group when NMFS approves a proposed CDP. A CDQ means the annual amount of a particular CDQ species that a CDQ group is permitted to catch based on a CDQ allocation that has been requested in a proposed CDP and approved by NMFS. A PSQ allocation means a percentage of a PSQ reserve that is assigned to a CDQ group. PSQ means the annual amount of a prohibited species that is allocated to a CDQ group based on a PSQ allocation.

CDQ Program Responsibilities

The proposed multispecies CDQ program would be a Federal program in which the fishing privileges for CDQ are temporarily allocated by NMFS to the CDQ groups. In return, the CDQ groups would be responsible for managing the CDQ harvesting and the CDQ projects as outlined in the CDPs on behalf of the member communities. NMFS would have no obligation to allocate future CDQ or PSQ based on past allocations, and CDQ and PSQ fishing privileges would expire with the expiration of a CDP. NMFS would base its awards of CDQ and PSQ allocations to the CDQ groups on the merits of the proposed CDPs.

The proposed CDPs, developed by the CDQ groups, would be the means for requesting CDQ and PSQ allocations from NMFS. Although NMFS would award the CDQ allocations to the CDQ groups, the CDQ groups would make the allocation requests on behalf of the eligible community(ies) that is (are) participating in the CDQ group. Therefore, a CDQ group would have a fiduciary responsibility to manage its CDQ allocations, CDQ projects, and assets in the best interests of the participating CDQ community(ies).

A CDQ community would be represented in a CDQ group in two ways. First, each CDQ group's Board of Directors (Board) would be required to have one voting member elected by his

or her community for each community in the CDQ group. Second, the managing organization (either the Board or a managing group contracted by the Board) would have to have a letter of support from each participating community before NMFS could award a CDQ allocation to the CDQ group.

To assure that the CDQ group's business decisions represent the interests of the CDQ community, the community-elected board member would vote on the Board in a way that reflects the community's wishes. During the election of a Board member, the CDQ community would have the opportunity to review the activities of its board member and its CDQ group, and evaluate the board member's performance. Further, a CDQ community could refuse to issue a letter of support for the CDQ managing organization for a proposed CDP and join another CDQ group or form a new CDQ group.

A CDQ group could manage the day-to-day business affairs of its CDP itself through its Board or could choose to contract with a managing organization. If a CDQ group were to contract with a managing organization, the CDQ group would be responsible for overseeing the managing organization's activities and would be held accountable by NMFS for all the managing organization's actions related to CDP management.

CDQ Application Process

Under the proposed multispecies CDQ program, the State would announce a CDQ application period, during which the CDQ groups would submit proposed CDPs to the State. The State would then hold a public hearing at which the CDQ groups would present their proposed CDPs and give the affected public an opportunity to comment. After the public hearing, the State would develop recommendations for the approval of proposed CDPs, consult with the Council, and submit the State's recommendations to NMFS for review and approval or disapproval.

The CDP would be submitted to NMFS by October 7 to provide sufficient time for NMFS to review the CDPs and to approve final CDPs and their CDQ allocations by December 31 of the application year.

The Community Development Plan

The CDP would provide information to the State and NMFS about the eligible communities, the managing organization, the CDQ projects, the requested allocation of CDQ and PSQ species, the harvesting and processing partners, and how the CDQ group would

account for CDQ and PSQ catches by these partners.

For each allocation request, § 679.30(a)(4) would require that the CDP identify the primary target fisheries by species and gear type, percentage of the target species requested, and the percentage of CDQ and PSQ species needed as bycatch in these fisheries.

The fishing plan (part of the CDP) described at § 679.30(a)(5) would be used to obtain information about the harvesting and processing partners in the groundfish and halibut CDQ fisheries. Specifically, the fishing plan would be required to contain a list of vessels and processors that the CDQ group proposed to authorize to participate in its groundfish and halibut CDQ fisheries and information about how the catch of CDQ and PSQ by these vessels and processors would be determined. The U.S. Coast Guard and NMFS Enforcement would use the list of eligible vessels and processors to determine whether vessels or processors were legally participating in the CDQ fisheries.

A vessel or processor would be required to be listed as an eligible vessel in an approved CDP in order to harvest or process groundfish or halibut CDQ for a particular CDQ group. In addition to this requirement, any vessel or processor with special equipment requirements such as certified scales to weigh catch or an observer sampling station also would be required to undergo a vessel or plant inspection and be permitted by NMFS to participate in the CDQ fisheries. Vessels or processors with no additional equipment requirements would not be required to be permitted by NMFS. They would be eligible to participate in the CDQ fisheries upon approval of a CDP in which they were listed. More information about vessel and processor categories, equipment requirements, vessel and plant inspections, and permitting requirements are contained in a later section.

The fishing plan also would specify how the CDQ group intended to make the estimates of CDQ and PSQ catch required to be reported to NMFS on the CDQ Catch Report. NMFS proposes to require each CDQ group to commit to a specific source of data and method for determining the weight or numbers of CDQ and PSQ catch by vessels fishing under its CDP, to identify the method in its CDP, and to amend the CDP before changing the source of data or method. CDQ groups would be prohibited from using any source or method other than that specified in the CDP and approved by NMFS to report CDQ and PSQ catch on the CDQ Catch Report.

Section 679.32(e)(3) sets forth NMFS' standard data sources for verifying catch estimates. If a CDQ group designates in its CDQ application, in accordance with the requirements of § 679.30(a)(5), the standard data sources set forth at § 679.32(e)(3) (and, if a catcher vessel using non-trawl gear, specifies whether it will be discarding CDQ species at sea), no specific approval by NMFS of the use of the data sources or method would be necessary. However, if the CDQ group desires to use an alternative procedure such as sorting and weighing all catch by species on processor vessels or using larger sample sizes than would be required under § 679.32(e)(3), it must, in accordance with the requirements of § 679.30(a)(5), propose the use of the specific alternatives it wishes to use. The CDQ group would have to demonstrate that space is available on the processor vessel to store, sort, and weigh the proposed sample sizes and that additional observers would be provided to accomplish the increased sampling or monitoring of sorting and weighing by species. The group would also have to demonstrate, and NMFS so find, that the alternative will produce equivalent or better estimates, that each haul, set or pot on an observed vessel can be sampled by an observer for species composition, that, if catch is to be sorted before it is weighed, the sorting and weighing process will be monitored by an observer, the observer will be required to be on duty no more than 12 hours in each 24-hour period and will be required to sample no more than 9 hours in each 24-hour period, and if the vessel uses trawl gear, the observer will be required to sample no more than 3 hauls in each 24-hour period. NMFS will review any proposed alternative and approve it in writing upon making the requisite determinations. An alternative can not be used unless specifically approved by NMFS. Alternatives to the requirement for a certified scale or for an observer sampling station will not be approved.

NMFS would require the CDQ groups to commit to the source of information and the procedures that would be used to estimate CDQ and PSQ catch for several reasons. First, discussion of the specific catch accounting requirements and the differences among the various vessel and processor types would help to identify and resolve conflicts prior to the start of CDQ fishing. NMFS wants to minimize the conflicts and decisions that have to be addressed between the harvesting and processing partners and the CDQ observers after fish have been harvested. Second, NMFS wants to

provide a means for vessels and processors to suggest alternative catch accounting methods that could improve catch estimates or work better for a particular vessel or plant. However, if different methods would be used, NMFS would need time to examine the proposals and specify conditions necessary to assure accurate CDQ catch estimates and reasonable working conditions for the CDQ observers. Finally, determining how catch estimates would be made in advance of the fishery would improve observer training.

Management of the Groundfish and Halibut CDQ Fisheries

Closures

All closures for the BSAI listed in § 679.22(a) would apply to the CDQ fisheries. As that section provides, the CDQ fisheries are specifically exempted from closure of the Catcher Vessel Operational Area to catcher/processors.

Seasons

The provision for closure of all trawl fisheries in the BSAI between January 1 and January 20 at § 679.23(c) would remain in effect for the CDQ fisheries.

Transfers of CDQ Allocations or CDQ

Once a proposed CDP is approved by NMFS and becomes effective, the proposed multispecies CDQ program would allow CDQ groups to transfer CDQ allocations, CDQ, PSQ allocations, and/or PSQ, from one to another, with certain restrictions.

CDQ Allocation. Any amount of a CDQ allocation could be transferred by both groups filing substantial amendments to their respective CDPs. The proposed requirements for a substantial amendment to a CDP appear at § 679.30(g)(4). The transfer would become valid on January 1 of the calendar year following the approval of the amendments, and the transfer would be valid for the duration of the CDPs.

CDQ. CDQ could be transferred in two different ways, and the transfer would be effective only for the calendar year in which the transfer occurs. First, 10 percent or less of a CDQ could be transferred in a calendar year by a CDQ group to another by using the technical amendment process. The proposed requirements for a technical amendment to a CDP appear at § 679.30(g)(5). Second, more than 10 percent of a CDQ could be transferred through the substantial amendment process.

PSQ allocations. A PSQ allocation could be transferred by substantial amendment, but the transfer would have to be accompanied by a transfer of a

CDQ allocation. NMFS would accept substantial amendments for the transfer of PSQ allocations only during the month of January. The transfer of a PSQ allocation would be effective for the duration of the CDPs.

PSQ. A PSQ allocation could be transferred by substantial amendment, but the transfer would have to be accompanied by a transfer of a CDQ allocation. NMFS would accept substantial amendments for the transfer of PSQ allocations only during the month of January. The transfer of PSQ would be effective only for the remainder of the calendar year in which the PSQ transfer occurs.

CDQ Non-Specific Reserve

Bycatch of some species is expected to constrain the groundfish CDQ fisheries and may even result in a CDQ group reaching the CDQ or PSQ for a bycatch species before it has harvested all of its target species CDQ. Therefore, NMFS proposes to create a non-specific reserve within the CDQ program to reduce the potential for the catch of some groundfish species to limit overall CDQ catch. CDQ species eligible to be placed in the non-specific reserve are low-valued species for which no target fishery currently exists but for which there is a sufficient buffer between the TAC and ABC. A buffer between TAC and ABC is required because use of the non-specific reserve may result in overall CDQ catches for a particular species in excess of the 7.5 percent allocation to the CDQ program. Only squid, arrowtooth flounder, and "other groundfish" meet the criteria for the CDQ non-specific reserve.

Each year, 15 percent of each CDQ group's arrowtooth flounder, squid, and "other groundfish" CDQ would be placed into a non-specific reserve for each CDQ group. A CDQ group would apply for a release from its CDQ non-specific reserve to its squid, arrowtooth flounder, or "other species" CDQ through the technical amendment process.

Prohibited Species Catch Management

The management of prohibited species catch in the groundfish CDQ fisheries would be modeled after the requirements of the non-CDQ groundfish fisheries. One exception would be that halibut PSQ would not be allocated between trawl and non-trawl gear. This would give CDQ groups more flexibility in their use of halibut PSQ. Catches of herring, salmon, or crab PSQ species by vessels fishing with non-trawl gear and catch of halibut PSQ by vessels using pot gear would not accrue to the respective PSQs. The only catch

to accrue against the non-chinook salmon PSQ would be catch of non-chinook salmon by vessels using trawl gear from August 15 through October 14 in the Catcher Vessel Operational Area as defined in existing § 679.2. The only catch to accrue against the chinook salmon PSQ would be catch of chinook salmon by vessels using trawl gear from January 1 through April 15.

Attainment of the herring, salmon, and crab PSQs by a CDQ group would result in the same time and area closures required for the open access fisheries in § 679.21. Specifically, vessels fishing under a CDP would be prohibited from:

1. Using trawl gear to harvest groundfish CDQ in Zone 1 once the PSQ for red king crab or *C. bairdi* Tanner crab in Zone 1 is reached.
2. Using trawl gear to harvest groundfish CDQ in Zone 2 once the PSQ for *C. bairdi* Tanner crab in Zone 2 is reached.
3. Using trawl gear to harvest groundfish CDQ in Herring Savings Areas (HSA) once the herring PSQ is reached.
4. Using trawl gear to harvest groundfish CDQ in the Chinook Salmon Savings Area from January 1 through April 15 once the chinook salmon PSQ is reached.
5. Using trawl gear to harvest groundfish CDQ in the Chum Salmon Savings Area between September 1 and October 14 once the non-chinook salmon PSQ is reached.

The CDQ representative would be responsible for monitoring the catch of prohibited species by vessels fishing under its CDP and for assuring that vessels using trawl gear stop fishing in the closed areas once the PSQ has been reached.

Attainment of the halibut PSC limit in the non-CDQ groundfish fisheries triggers closure of groundfish fishery categories to directed fishing. However, no fishery categories or gear allocations are proposed for halibut PSQ. Therefore, the halibut PSQ would be treated the same as groundfish or halibut CDQ. The CDQ groups would be prohibited from exceeding their halibut PSQ.

NMFS is proposing that catcher vessels using trawl gear be required to retain all salmon and herring PSQ and deliver them to a processor where they would be sorted and weighed on a certified scale. Retention of salmon and herring PSQ would eliminate the need for the vessel operator or the CDQ observer to estimate the weight or numbers of at-sea discards, thereby improving accounting for these PSQ species. Unlike halibut and crab, salmon and herring are believed to have 100

percent mortality when harvested with trawl gear, so NMFS anticipates that no additional mortality of these species would result from the retention requirement.

Section 679.21 would be amended to allow the retention of herring and salmon PSQ by catcher vessels using trawl gear in the CDQ fisheries until the PSQ is sorted and weighed on a certified scale by a processor. The State would have to change its regulations to allow the retention and delivery of these species to shoreside processing plants.

In order for the multispecies CDQ regulations to reflect the State of Alaska's administration of the CDQ program, all references to the Governor of the State have been removed and the "State of Alaska" inserted in their places.

In § 679.2, the definition of "Governor" is removed and a definition of "State" is added.

Improved Retention/Improved Utilization

Regulations governing the retention or utilization of groundfish species in the non-CDQ fisheries also would apply to the groundfish CDQ fisheries.

Vessel Incentive Program

NMFS proposes that catch in the groundfish CDQ program not be subject to the Vessel Incentive Program (VIP) regulations in § 679.21(f). CDQ groups would receive individual allocations of prohibited species catch allowances and would be responsible for managing their fisheries within these limits.

Recordkeeping and Reporting Requirements for CDQ Groups

Each CDQ group would be responsible for collecting and reporting catch data for all vessels and processors participating in its CDQ fisheries. This would enable each group to directly manage its CDQ fisheries and to be held accountable for staying within CDQ and PSQ allocations.

All vessels and processors participating in the CDQ fisheries would be required to continue to comply with all other recordkeeping and reporting requirements in § 679.5, such as maintaining logbooks and preparing weekly production reports. Among other requirements, CDQ catch would have to be reported separately from other catch on these reports, along with the CDQ group number.

The CDQ Check-In/Check-Out Report

The CDQ representative would be required to submit a CDQ check-in/check-out report to notify NMFS when vessels participating in the CDQ

fisheries begin and stop CDQ fishing throughout the year. The notification also would help NMFS track whether the appropriate CDQ catch reports were being submitted.

A check-in report would be required prior to the first CDQ fishing of the year and any time during the year CDQ fishing started again after a CDQ check-out report had been submitted. A CDQ check-out report would be required when any vessel switched between CDQ and non-CDQ fishing, stopped CDQ fishing for the remainder of the year, or was removed as an eligible vessel from a CDQ. The CDQ check-in/check-out report is described at § 679.5(m).

The CDQ Catch Report

The CDQ group would submit a weekly CDQ catch report for each vessel fishing CDQ. NMFS would maintain a record of the cumulative CDQ and PSQ catch based on the information submitted in the CDQ catch report. The CDQ catch report is described at § 679.5(n). NMFS would monitor the accuracy and completeness of the CDQ catch reports by using information from the CDQ check-in/check-out reports, vessel and processor reports, and observer data. NMFS would make an independent estimate of CDQ and PSQ catch for each CDQ group using the catch accounting procedures agreed upon in the CDP.

Attaining or Exceeding a CDQ or PSQ

CDQ and PSQ allocations would be made to CDQ groups, not to individual vessels or processors. Each CDQ group would be responsible for preventing the exceeding of CDQs and halibut PSQ and for complying with time and area closures triggered by attainment of the salmon, herring, and crab PSQs. Therefore, the CDQ group would be primarily responsible for monitoring its harvesting and processing partners to account for all CDQ and PSQ and for taking actions necessary to prevent exceeding CDQs or halibut PSQs. Although NMFS would monitor CDQ fishing in season and provide information to the CDQ groups, NMFS would not prescribe specific actions to avoid exceeding CDQ or PSQ.

Inseason monitoring of CDQ catches would be based on the weekly CDQ catch report submitted by the CDQ representative. Also, NMFS would estimate the CDQ and PSQ catches from reports submitted by vessels and processors, such as the ADF&G fish tickets and processor's weekly production reports and by observers. The official estimates of CDQ and PSQ catch would be made once all observer

data was verified by NMFS and the CDQ catch reports reviewed.

CDQ Catch Accounting Requirements for Vessels and Processors

Proposed catch accounting requirements including equipment, observer coverage, and procedures for estimating catch are discussed below by vessel and processor type. Additional information about the specific requirements for certified scales to weigh catch at sea, certified bins for volumetric estimates, the observer sampling station, and certified CDQ observers are discussed in later sections.

Unobserved Catcher Vessels

Catcher vessels in the groundfish and halibut CDQ fisheries that are less than 60 ft (18.3 m) LOA would not be required to carry a CDQ observer. The majority of unobserved vessels participating in the current CDQ fisheries are catcher vessels harvesting halibut CDQ that are 32 ft (9.8 m) or less LOA. In an analysis prepared for the April, 1996 Council meeting, NMFS estimated that, of the 127 catcher vessels harvesting halibut CDQ in 1995, 120 were 32 ft (9.8 m) or less LOA, one was between 33 ft (10.1 m) and 59 ft (18.0 m) LOA, and six were between 60 ft (18.3 m) and 124 ft (37.8 m) LOA. In the 1995 sablefish CDQ fisheries, one catcher vessel was less than 60 ft (18.3 m) LOA and two were between 60 ft (18.3 m) and 120 ft (36.6 m) LOA.

The catch accounting expectations of the multispecies CDQ fishery would require that the catch of all CDQ and PSQ species by unobserved vessels be counted against a CDQ or PSQ allocation. However, it is difficult to obtain accurate and reliable estimates of the catch of species discarded at sea by unobserved vessels.

NMFS proposes to require unobserved vessels to retain all CDQ species and deliver them to a processor where they would be sorted and weighed on a certified scale. Catcher vessels using trawl gear would be required to retain all salmon and herring PSQ and deliver it to the processor. All catcher vessels would be required to carefully release halibut PSQ, record the estimated weight of the halibut PSQ, and report this on the ADF&G fish ticket and to the CDQ representative.

NMFS considered requiring the use of bycatch rate assumptions developed from observer data on vessels in the same target fishery and gear type as the unobserved vessels. However, NMFS decided not to propose this approach because it would require estimation of bycatch rates with very little observer data, particularly for the halibut CDQ

fisheries, which make up the majority of the unobserved vessels at this time. NMFS also decided against proposing that the CDQ groups provide for some level of observer coverage on the unobserved vessels because of safety and cost concerns about deploying observers on such small vessels and out of remote communities.

Unobserved catcher vessels would not have additional equipment requirements that would necessitate a vessel inspection. Therefore, they would not require a CDQ permit. They would be eligible to participate in the CDQ fisheries as long as they were listed as eligible vessels in an approved CDP.

Observed Catcher Vessels

All catcher vessels 60 ft (18.3 m) and greater LOA would be required to have at least one certified lead CDQ observer (described in a later section) for all groundfish and halibut CDQ fishing.

Observed Catcher Vessels Using Trawl Gear

Operators of observed catcher vessels using trawl gear would be required to retain all groundfish CDQ and salmon and herring PSQ and deliver it to a processor where it would be sorted and weighed on a certified scale. All halibut and crab PSQ would be required to be discarded at sea after the observer had counted the halibut and crab PSQ and taken length measurement of the halibut.

NMFS is proposing that all groundfish CDQ and salmon and herring PSQ be retained and weighed at a processing plant to eliminate the need for an observer to estimate the weight or numbers of at-sea discards. Without a means to weigh a large quantity of catch on the vessel, observers on board catcher vessels using trawl gear cannot make accurate estimates of at-sea discards.

NMFS' proposed standard sources for estimating catch are the observer's estimate of halibut PSQ weight and crab PSQ numbers and on ADF&G fish tickets for the weight or numbers of CDQ and PSQ species.

Vessel owners would be required to provide space on the deck of the vessel for the observer to sort and store catch samples and a place from which to hang the observer sampling scale. Catcher vessels using trawl gear and retaining all groundfish CDQ and salmon and herring PSQ would not have additional equipment requirements that would necessitate a vessel inspection. Therefore, they would not require a CDQ permit. They would be eligible to participate in the CDQ fisheries as long

as they were listed as eligible vessels in an approved CDP.

Observed Catcher Vessels Using Non-Trawl Gear

Observed catcher vessels using longline, pot, and jig gear (non-trawl gear) could select one of two options for estimating groundfish and halibut CDQ. The first option would be to retain all groundfish and halibut CDQ (as is required for observed catcher vessels using trawl gear) and deliver it to a processor with a certified scale. Catcher vessels using this option would not be required to have a CDQ permit. The second option would allow groundfish CDQ to be discarded at sea under the same requirements applicable to processor vessels using non-trawl gear under this option. In this case, the catcher vessel operator would have to provide sufficient observer coverage to sample all CDQ sets for species composition and average weight. In addition, the vessel would be required to have an observer sampling station with a motion-compensated sampling scale so that observers could obtain accurate average weight data on each species in the catch (see discussion below). Under this option, catcher vessels using this option would be required to have a CDQ permit and a vessel inspection to check the sampling station and scale.

In both cases, careful release of halibut PSQ would be required and the observer would estimate the weight of halibut PSQ.

NMFS' proposed standard sources and procedures for verifying the catch for vessels retaining all groundfish CDQ are or would use the observer's estimate of halibut PSQ weight and the vessel operators' and processors' reports of weight or numbers of CDQ and PSQ catch reported on ADF&G fish tickets.

NMFS' proposed standard procedures for estimating catch for vessels discarding groundfish CDQ at sea would use the observer's estimate of the weight of both groundfish CDQ and halibut PSQ.

Catcher/Processors and Motherships

Regardless of their length, all catcher/processors and motherships would be required to have at least two certified CDQ observers, one of whom must meet the requirements of a lead CDQ observer (see discussion below).

All catcher/processors and motherships would be required to provide special equipment for estimating CDQ and PSQ catch. Any vessel required to have a certified scale, certified bins, or an observer sampling station would have to be inspected and

receive a special permit prior to being permitted to participate in the CDQ fisheries. Therefore, being listed as an eligible vessel in an approved CDP would not be sufficient for a catcher/processor or mothership to fish CDQ. The proposed inspection and the CDQ permit requirements are described in a later section.

Catcher/Processors Using Trawl Gear and Motherships

Catcher/processors using trawl gear and motherships would be required to weigh all catch in the CDQ fisheries on a scale certified by NMFS and to have an observer sampling station. Proposed regulations governing the certified scales and the observer sampling station are described in a later section.

NMFS' proposed standard sources and procedures for estimating catch for these vessels are or would use the observer's report of total catch weight from the certified scale and the observer's species composition sample data.

Catcher/Processors Using Non-Trawl Gear

Catcher/processors using longline, pot, or jig gear would be required to have an observer sampling station, including a motion-compensated platform scale. CDQ observers would sample each set and determine species composition and average weight for all CDQ and PSQ species.

NMFS' proposed standard sources for estimating catch for these vessels are the observer's report of species composition and average weight.

Shoreside Processors

Shoreside processors would be required to sort all CDQ deliveries by species or species group and weigh them on a scale certified by the State. PSQ species monitored by number would be required to be counted. The sorting and weighing of all CDQ and PSQ would be required to be monitored by a CDQ observer.

Shoreside processors would be required to be listed in the CDP and to have a valid CDQ permit to accept deliveries of CDQ catch. The permit would not be issued until NMFS had determined that the CDQ catch could be weighed on a certified scale and that an observer could monitor the sorting and weighing of all CDQ species.

Observer Sampling To Determine CDQ and PSQ Catch Weight

Methods proposed by NMFS that would be based on observer sampling to estimate species composition of the catch would use sample sizes and

procedures that NMFS believes an observer could reasonably accomplish in the time available to him or her under the fishing and processing conditions on a vessel. Observers would obtain the largest sample sizes they can, given time, equipment, available space, and catch composition. NMFS is not proposing to specify minimum sample sizes necessary to obtain catch weight estimates with specific statistical qualities. The staff resources and data necessary to develop sampling plans appropriate for specific target fisheries or specific vessels are not available at this time. In addition, NMFS expects that the minimum sample sizes required to estimate the weight of infrequently occurring species on a haul-by-haul basis with a high level of confidence would be too large to accommodate in the space available on many vessels and would require more than two observers to sort and weigh. If NMFS develops sampling plans or minimum sample sizes for the groundfish fisheries as a whole in the future, this information could be added to the CDQ fishery requirements at that time.

Separation of CDQ and Non-CDQ Catch

The need to account for all halibut, groundfish TAC species, and prohibited species under the groundfish and halibut CDQ program necessitates the separation of CDQ catch, IFQ catch, and non-CDQ catch. NMFS must be able to distinguish between CDQ and non-CDQ fishing in order to know whether catch accrues to a CDQ/PSQ or to IFQs or non-CDQ TACs and PSC limits. Therefore, catcher vessels could land and deliver CDQ and IFQ species together, but they would be prohibited from catching and delivering CDQ and non-CDQ catch together. Catcher/processors would be prohibited from mixing CDQ and non-CDQ catch in the same haul or set. In addition, observed catcher vessels and catcher/processors could not harvest fish for more than one CDQ group or from CDQ and IFQ in the same haul or set. Observed catcher vessels could harvest CDQ and IFQ fish in different sets on the same trip if they had sufficient quota to cover their catch of all species.

On catcher/processors allowed to retain both CDQ and non-CDQ catch during the same trip, no CDQ catch or processed product from CDQ catch could be used as a basis species to determine maximum retainable bycatch amounts in the non-CDQ fisheries.

Equipment Requirements for Vessels

A new § 679.28 entitled "Equipment and Operational Requirements for Catch Weight Measurement" proposed in a

separate rulemaking would set forth the requirements for certified scales to weigh catch at sea and certified scales in shoreside processing plants (62 FR 32564, June 16, 1997). This proposed rule would modify that proposed rule by adding requirements for observer sampling stations to § 679.28 and moving the requirements for certified holding bins from subpart C to § 679.28. Although these equipment and operational requirements are proposed only as part of the CDQ monitoring program at this time, they may be applied more widely in the future.

Certified Scales

All CDQ catch harvested by trawl catcher/processors or delivered to processor vessels or shoreside processing plants would be required to be weighed on a certified scale to obtain the most accurate estimate of the weight of each CDQ and PSQ species. Catch by observed vessels using non-trawl gear could be estimated by counting individual species and applying an average weight. Scales in shoreside processing plants would be required to be certified by the State of Alaska, as they currently are required to be under State law. Scales on catcher/processors using trawl gear and motherships would be certified under NMFS' at-sea scale certification program. More discussion on the background and requirements of the at-sea scale certification program may be found in the preamble to the at-sea scale certification proposed rule (62 FR 32564, June 16, 1997).

All trawl catcher/processors and motherships would be required to install a scale and have the scale certified by a weights and measures inspector authorized by the Administrator, Alaska Region, NMFS (Regional Administrator). All of the catch would be required to be weighed on the certified scale before it is sorted. The weight of each species would be determined by the observer's species composition sampling unless some other method is approved by NMFS in the CDP.

Purchase of a scale appropriate for trawl processor vessels may cost between \$30,000 (hopper scales) and \$50,000 (belt-conveyor scales). Installation costs will vary depending on the type of scale selected, the modifications necessary to accommodate the scale, and changes in the sorting and discarding operations. In 1994, the Council recommended that NMFS require at-sea scales on processor vessels in the BSAI pollock fisheries. A draft EA/RIR/IRFA prepared for that recommendation analyzed an alternative to requiring certified scales

on all trawl processor vessels. NMFS estimated that installation of an at-sea scale could cost from \$5,000 to \$250,000 per vessel. A copy of this EA/RIR/IRFA may be obtained from the Regional Administrator (see **ADDRESSES**). The installation of a scale also may reduce the efficiency of the fish processing factory, particularly if processing equipment has to be relocated. Although NMFS cannot estimate what these costs may be, processor vessels that would have to undergo significant modifications to their vessels or forego substantial processing efficiencies to accommodate a scale probably would choose not to participate in the CDQ fisheries rather than incur these costs.

Observer Sampling Station

All processor vessels would be required to have an observer sampling station that includes a motion-compensated scale to improve the accuracy of sample weights, a table, a hose that supplies fresh or salt water, and a specified minimum amount of work space. Current observer sampling scales do not compensate for vessel motion and, therefore, are not providing as accurate sample weights as could be obtained with a motion-compensated scale. In addition, many processor vessels currently do not provide working and storage space necessary for observers to carry out their duties. The observer sampling station is estimated to cost between \$8,000 and \$14,000 per vessel, the majority of which is due to the motion-compensated platform scale which could cost between \$8,000 and \$12,000 each.

Certified Bins for Volumetric Estimates

The regulations governing the use of certified holding bins for volumetric estimates of total catch weight on catcher/processors and motherships are proposed to be moved from subpart C to the new § 679.28(e). Although processor vessels in the CDQ fisheries would be allowed to use certified bins for volumetric estimates of pollock CDQ catch in 1998 only, requirements for certified bins must remain in regulation because NMFS allows processor vessels in the non-CDQ pollock fisheries with certified bins and two observers to use only observer estimates, rather than the NMFS blend system, to determine pollock catch weight.

NMFS implemented regulations in a final rule published on May 16, 1994 (59 FR 25346) requiring processor vessels participating in the pollock CDQ fisheries to have certified bins for volumetric estimates. A more complete description of how certified bins are used by observers to make volumetric

estimates of total catch weight is included in the preamble to the proposed rule referenced above and in the preamble to the then-proposed rule for certified bins (58 FR 68386, December 27, 1993).

The current certified bins regulations include equipment and operational requirements. The operator is required to have each holding bin that would be used for volumetric estimates measured, marked, and certified by an independent marine engineer or other authorized individual. The operator also is required to provide "visual access" to the bins so that the observer can see the level of fish throughout the bin from outside the bin. In addition to the certification requirements, operators also must comply with operational requirements such as notifying the observer when fish would be added to or removed from the bin, or not filling the bin above the viewing port.

The following changes are proposed for the new paragraph at § 679.28(e) on certified bins:

(1) The paragraph would be reorganized to separate specifications and certification requirements from operational requirements.

(2) Certification documents would be required to be submitted to the Regional Administrator (as would all equipment certification requirements in § 679.28) rather than to the NMFS Observer Program Office as required under current regulations.

(3) A new requirement that numerals identifying the level of fish in the bins be at least 4 cm high would be added for bin certification documents dated 30 days after the effective date of the final rule. Because the bin certification requirements would be effective only for 1998 in the CDQ fisheries, NMFS does not believe that vessel owners should be required to modify numerals on previously certified bins. However, any bins certified for the first time or recertified after the effective date of this proposed rule would be required to comply with this requirement.

(4) Clarification that marked increments would not be required on the wall in which the viewing port is located unless they are needed to determine the level of fish from another viewing port.

(5) A specific list of information that must be included in bin certification documents submitted after the effective date of this proposed rule would be added. In the current regulations, the bin certification documents must include a description of the location of bin marks, tables indicating bin volume in cubic meters for each marked increment and must be dated and signed

by the person preparing the documents. This proposed rule would add the vessel name, the date the bins were measured and the marked increments and numerals were witnessed, a diagram of the location of the marked increments, the location and dimensions of each viewing port, and instructions for determining the volume of fish in each bin from the diagrams and tables.

(6) A new requirement that refrigerated seawater tanks could be used for volumetric estimates only if all other requirements of the paragraph were met and no water had been added to the bins before the observer made a volumetric estimate.

(7) The requirement for a viewing port or ports, through which the level of fish inside the bin can be seen from outside the bin, would be more clearly stated.

(8) The provision allowing bins to be certified by "a qualified organization that has been designated by the USCG Commandant, or an authorized representative thereof, for the purpose of classing or examining commercial fishing industry vessels under the provisions of 46 CFR 28.76 would be removed. NMFS believes that it is sufficient to require that a registered engineer perform bin certifications.

Equipment That Biases Observer Samples

Estimates of the catch of CDQ and PSQ would be based either on processors' reports of sorted and weighed or counted catch or on the observer's species composition sample data applied to total catch weight. In either case, the use of equipment that would remove or destroy fish before they are counted, weighed, or sampled would result in an inaccurate estimate of CDQ or PSQ catch. In the shoreside plants, these fish would not be sorted and weighed or counted. On a vessel, removal of these fish would bias the observer's sample. NMFS regulations currently contain a prohibition at § 679.7(g)(2) against interfering with or biasing the sampling procedure employed by an observer, including physical, mechanical, or other sorting or discarding of catch before sampling. Although no additional specificity is being proposed at this time, NMFS believes that the following equipment biases observer samples if used to transport fish prior to the time the fish reaches the location where the observer samples: Pumps that grind fish; grates, small pipes, and hatches that prevent larger fish from flowing through; and incline belts operated at certain angles or speeds so that some fish do not get transported up the belt. NMFS may

consider adding specific prohibitions against the use of such equipment in the future.

Permits for Vessels and Processors in the CDQ Fisheries

The catch accounting requirements for the groundfish and halibut CDQ programs are different from those for the non-CDQ fisheries because they require the use of new equipment on vessels and observer monitoring of sorting and weighing of CDQ catch in shoreside plants.

All shoreside processors and all vessels required to have equipment such as a certified scale to weigh catch or an observer sampling station would be required to obtain a permit from NMFS to participate in the groundfish or halibut CDQ fisheries. Prior to issuing the CDQ permit, NMFS would inspect each vessel and processing plant to verify that the equipment required to account for CDQ catch was present and operational on the vessel and that specific requirements for observer sampling or sorting and weighing of catch could be met.

NMFS' experience with the certified bin requirement in the pollock CDQ fisheries is an important factor in NMFS' recommendation for pre-fishing inspections. Problems with the certified bins include improperly certified bins, inability of observers to see into the bins, unsafe access to the bins, and lack of understanding about how to use the bin certification documents. These problems have caused conflicts between vessel operators and the observers. Communication difficulties and the fact that many of the problems are only identified once fish have been harvested and the observer is unable to make a volumetric estimate of total catch weight have made it difficult to resolve the problems quickly. Some of these problems could have been identified and resolved by a vessel inspection and improved communication between the CDQ participants and NMFS before CDQ fishing started. Other problems are operational in nature and cannot be identified until a vessel is fishing. The CDQ permit would be used only to identify compliance with specific equipment requirements prior to the start of the CDQ fisheries. NMFS would still have to rely on reports by observers or authorized officers to enforce operational violations.

Trawl catcher/processors and motherships would be inspected to verify that the observer sampling station meets the requirements of § 679.28(d), that the motion-compensated observer sampling scale is operating properly, and that observers can sample unsorted

catch after it has been weighed on a certified scale.

Longline and pot catcher/processors and catcher vessels would be inspected to verify that the observer sampling station meets the requirements of § 679.28(d) and that the motion-compensated observer sampling scale is operating properly.

Shoreside processors would be inspected to verify that an observer can monitor the sorting and weighing of all CDQ and PSQ catch on a scale certified by the State of Alaska.

Vessel owners or processors would be required to submit a permit application to NMFS. Trawl catcher/processors and mothership owners and shoreside processors would be required to submit a diagram and description of the vessel or processing plant showing where CDQ catch would be sorted and weighed on a certified scale and the location of the observer sampling station on vessels. Trawl catcher/processors and mothership owners also would be required to submit a copy of the at-sea scale inspection certificate. Longline or pot catcher/processors or catcher vessels would not be required to submit supplemental information with the permit application.

Upon receipt of the permit application, NMFS would schedule a vessel or plant inspection. NMFS would not issue the permit until the vessel or plant inspection had been conducted and NMFS verified compliance with specific equipment and catch accounting requirements.

Permits would have to be renewed each year. However, after the initial inspection of a vessel or plant has been conducted, NMFS could waive requirements for inspections in future years if the observers report no problems with equipment or operational requirements and if the annual scale certification documents required for vessels are received by NMFS.

Once permitted, a vessel or processor could harvest or process CDQ fish for any CDQ group during the year for which it is permitted as long as it is listed as an eligible vessel or processor on the approved CDP for that CDQ group.

Certified CDQ Observer

The multispecies groundfish CDQ program would rely heavily on information collected by observers to determine the catch of CDQ and PSQ species, thereby increasing the need for accurate and timely observer data. Observers would need additional training and briefing to provide more in-depth information about the additional monitoring, equipment, and operational

requirements of the CDQ fisheries; how to collect and transmit CDQ data; and how to communicate questions or problems to NMFS. Therefore, NMFS proposes to create a new category of observer called a NMFS-certified CDQ observer, the requirements for which would be added at § 679.50(h)(1)(i) (D) and (E).

Two levels of CDQ observer are proposed. The first level would be called a "CDQ observer" and the second level a "lead CDQ observer." A person would be required to have experience observing in the CDQ fisheries in order to be certified as a lead CDQ observer. The CDQ observer level, with no requirements for CDQ observing experience, is necessary in order to provide the experience in the CDQ fisheries that is required to become a lead CDQ observer.

Both the CDQ observer and the lead CDQ observer would be required to have the following qualifications to be certified:

1. Receive the rating of 1 for "exceptional" or 2 for "meets expectations" by NMFS for their most recent deployment,
2. Have completed at least 60 days of observer data collection as a certified North Pacific groundfish observer on a vessel using the same gear type as the CDQ vessel that they will be deployed on. In other words, CDQ observers would be certified for specific gear types.
3. Successfully complete a NMFS-approved CDQ observer training and/or briefing. The additional training is expected to take approximately 5 days.

In addition to these requirements, a person certified as a "lead" CDQ observer would be required to have successfully completed at least 20 days of observer data collection on a vessel of any gear type participating in a CDQ fishery.

At least one of the observers on each catcher/processor, mothership, or catcher vessel and in the onshore processing plant would be required to be a certified "lead" CDQ observer. All CDQ observers on vessels would be required to have at least 60 days of experience collecting data on a vessel of the same gear type as the CDQ vessel they are deployed on.

Observer Coverage Requirements

Observer coverage requirements for vessels and processors participating in the groundfish and halibut CDQ fisheries would be moved from subpart C to subpart E with all other observer coverage requirements. Catcher vessels less than 60 ft (18.3 m) LOA would not be required to carry an observer. All

catcher vessels 60 ft (18.3 m) LOA or longer, including those catcher vessels fishing halibut CDQ with groundfish CDQ bycatch, would be required to carry at least one certified lead CDQ observer. Shoreside processing plants would be required to have at least one certified lead CDQ observer to monitor the sorting and weighing of all CDQ deliveries. Catcher/processors and motherships would be required to have two certified CDQ observers on board during the CDQ fisheries, at least one of whom would be required to be a certified lead CDQ observer. Processors purchasing halibut CDQ and no other groundfish are not required by NMFS to have Federal Processor permits and, therefore, are not required to be monitored by NMFS-certified observers. Observer coverage requirements include vessels fishing for halibut CDQ because of the need to monitor the catch of all CDQ and PSQ species in the catch.

This proposed rule also would amend § 679.50(a) to clarify that CDQ observer coverage days for "30 percent coverage" vessels would not count towards the required distribution of observer coverage throughout the year in the non-CDQ fisheries as described in § 679.50(c)(1)(v) and (c)(1)(vii).

Catch Accounting During the Transition Year

In 1998, processors in the pollock, sablefish, and halibut CDQ fisheries would continue to follow the catch accounting regulations currently used, although these regulations would be moved to § 679.32(f). Processor vessels in the pollock CDQ fishery would continue to use volumetrics to estimate pollock catch weight, however, pollock CDQ catches would be required to be reported to NMFS on the CDQ catch report.

Fixed gear vessel operators in the halibut and sablefish CDQ fisheries would be allowed to continue to use processed product weight and product recovery rates to estimate the round weight of retained catch and to report their catch to the RAM Division under the same regulations used for the halibut and sablefish IFQ program. The halibut and sablefish CDQ regulations would be moved to § 679.32(g). Halibut and fixed gear sablefish CDQ landings would not be reported on the CDQ catch report until 1999.

The Council recommended that bycatch from the pollock, fixed gear sablefish, or fixed gear halibut CDQ fisheries not accrue against the CDQ groups' CDQ or PSQs in the transition

year. The only species that would accrue to a CDQ in the pollock CDQ fisheries would be pollock. Similarly, only sablefish and halibut catch in the fixed gear sablefish and halibut CDQ fisheries would accrue against a CDQ. Catch of all other species in these CDQ fisheries would accrue to the respective non-CDQ TACs and PSC limits.

Different requirements for the various CDQ fisheries in 1998 require definitions to distinguish among them. In 1998, the multispecies CDQ fisheries would not include pollock, fixed gear sablefish, or halibut. Different CDQ numbers would be assigned to each CDQ group's allocations of pollock, sablefish, halibut, and multispecies groundfish. Under the current regulations, each vessel and processor is required to maintain separate catch and production records for fish harvested under each CDQ number. In addition, the CDQ representative would be required to identify vessels fishing in the pollock CDQ fisheries on the check-in and check-out reports. Check-in/check-out reports are not proposed to be required for the fixed gear halibut and sablefish CDQ fisheries in 1998, because they would still be operating under the IFQ regulations.

The allowable amount of groundfish bycatch that could be retained in the pollock, fixed gear sablefish, and fixed gear halibut CDQ fisheries would have to comply with maximum retainable bycatch amounts and fishery closures for the non-CDQ TACs against which this bycatch is accruing.

Equipment and operational requirements proposed for the multispecies CDQ program would not apply to the pollock and fixed gear sablefish and halibut CDQ fisheries in 1998. However, starting on January 1, 1999, the equipment and operational requirements discussed in previous sections would apply to all vessels and processors in the multi-species groundfish and halibut CDQ fisheries.

Classification

At this time, NMFS has not determined that the amendment that this rule would implement is consistent with the national standards of the Magnuson-Stevens Act and other applicable laws. Section 304(a)(3) of the Magnuson-Stevens Act requires NMFS to approve, disapprove, or partially approve an amendment submitted by the Council within 30 days of the end of the comment period for that amendment. NMFS, in making that determination, will take into account

the data, views, and comments received during the comment period.

This proposed rule has been determined to be not significant for purposes of E.O. 12866.

An EA/RIR was prepared for this rule that describes the management background, the purpose and need for action, the management action alternatives, and the socio-economic impacts of the alternatives. The EA/RIR estimates the total number of small entities affected by this action, and analyzes the economic impact on those small entities. Based on the economic analysis in the EA/RIR, the Assistant General Counsel for Legislation and Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities.

Although most fishing operations affected by these regulations (1,896 fishing operations—based on the total number of moratorium qualifications issued to date) are considered small entities, a substantial number of these small entities would not experience impacts of the type contemplated by the RFA as "significant." In fact, it is estimated that 2,962 fishing operations would qualify under the LLP, 1,066 more fishing operations than are currently licensed to operate. This number of fishing operations also exceeds the average number of fishing operations from 1988–1995 (1,956 fishing operations) and the fishing operations in the year of the highest participation (1992—2,285 fishing operations). Some vessels that are currently participating under the moratorium on entry might not qualify under the LLP because of insufficient participation during the endorsement qualification period (1992–1995). However, given the relatively easy qualification requirements (i.e., one landing in each of any 2 calendar years 1/1/92–6/17/95 at most, in some cases only a single landing during that period), this number is anticipated to be below the 20 percent threshold. Furthermore, most vessels that would not qualify for a license under the LLP would be small vessels that are either exempt from the LLP because of their size (i.e., equal to or less than 32 ft in the Bering Sea and Aleutian Islands Area or equal to or less than 26 ft in the Gulf of Alaska), or vessels that primarily participated in state waters and only had minimal participation in the EEZ off Alaska (i.e., landings that amounted to less than 5 percent of their gross catch). In the case of the former, there would be no impact, significant or otherwise, because these vessels would be able to continue their participation through the exemption provided in the

LLP. In the case of the latter, the impact would not rise to significance under the RFA because the vessels primarily participated in state waters, which would be unaffected by the LLP.

While the CDQ allocations certainly provide significant benefits to the recipient groups and communities, and at the same time impose additional reporting and administrative requirements, the six CDQ organizations likely would not be classified as "small entities" under the auspices of the RFA, nor would they, in total, comprise a "substantial" number of entities (large or small) operating in the fisheries off Alaska.

The associated 7.5 percent reduction in overall quota available to the remaining fishing fleet (which includes a substantial number of small entities) is not expected to result in a direct 7.5 percent reduction in catch, for example, by any individual small fishing operation. As noted previously, the 7.5 percent allocation is far less than the percentage of fish currently discarded in the collective groundfish fisheries. Council programs, which mandate retention and utilization of groundfish species beginning in 1998, are estimated to more than make up for the 7.5 percent quota reduction, in terms of overall fish available for both small and large fishing operations. It is also true that the gross income for individual, small fishing operations is less dependent on overall quotas available than it is on other factors such as, relative fish prices across species, unpredictable weather patterns, timing and magnitude of alternative fishing opportunities such as salmon, and other business decisions made independent of the overall TAC levels for groundfish.

As a result, a regulatory flexibility analysis was not prepared. Copies of the EA/RIR can be obtained from NMFS (see **ADDRESSES**).

This proposed rule contains new collection-of-information requirements subject to the Paperwork Reduction Act (PRA). These collection of information has been submitted to OMB for approval. The new information requirements consist of: Preparation of 5,000 initial applications over the life of the LLP requiring an estimated time of 2 hours each to complete for a total of 10,000 hours; preparation of 500 transfer applications per year requiring an estimated time of 1 hour each to complete for a total of 500 hours per year; preparation of six proposed CDPs requiring an estimated time of 500 hours to complete for an average of 1,000 hours per year; preparation of six annual reports requiring an estimated time of 40 hours to complete for a total of 240 hours per year; preparation of six annual budget reports requiring an estimated time of 20 hours to complete for a total of 120 hours per year; preparation of six annual budget reconciliation reports requiring an

estimated time of 8 hours to complete for a total of 48 hours per year; preparation of 48 substantial amendments requiring an estimated time of 8 hours to complete for a total of 384 hours per year; preparation of 60 technical amendments requiring an estimated time of 4 hours to complete for a total of 240 hours per year; preparation of 56 CDQ permit applications requiring an estimated time of 2 hours to complete for a total of 112 hours; preparation of 1,560 CDQ check-in/check-out reports requiring an estimated time of 10 minutes to complete for a total of 260 hours; preparation of 144 CDQ catch reports requiring an estimated time of 2 hours to complete for a total of 288 hours per year; preparation of 75 prior notices of offloading requiring an estimated 2 minutes to complete for a total of 2.5 hours per year; and printing and retention of 725 scale printouts by shoreside processors requiring an estimated time of 10 minutes to complete for a total of 121 hours per year, and reporting of at-sea discards on 650 ADF&G fish tickets by unobserved catcher vessels requiring an estimated time of 20 minutes to complete for a total of 217 hours per year. For 1998 only, information requirements consist of bin certifications requiring an estimated time of 8 hours to complete for a total of 0 hours for 1998; changes to the list of CDQ halibut/sablefish cardholders requiring an estimated time of 0.5 hours to complete for a total of 3.5 hours for 1998; and changes to CDP lists of vessels for halibut/sablefish requiring an estimated time of 1 hour for a total of 14 hours for 1998.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number.

Public comment is sought regarding: Whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including through the use of automated collection techniques or other forms of information technology. Send comments regarding burden estimates or any other aspect of the data requirements, including

suggestions for reducing burdens, to NMFS (see **ADDRESSES**) and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 (ATTN: NOAA Desk Officer).

List of Subjects in 50 CFR Part 679

Alaska, Fisheries, Reporting and recordkeeping requirements.

Dated: August 6, 1997.

Rolland A. Schmitten,

*Assistant Administrator for Fisheries,
National Marine Fisheries Service.*

For reasons set out in the preamble, 50 CFR part 679 is proposed to be amended to read as follows:

PART 679—FISHERIES OF THE EXCLUSIVE ECONOMIC ZONE OFF ALASKA

1. The authority citation for part 679 continues to read as follows:

Authority: 16 U.S.C. 773 *et seq.*, 1801 *et seq.*, and 3631 *et seq.*

2. In § 679.1, paragraph (e) is revised and paragraph (j) is added to read as follows:

§ 679.1 Purpose and scope.

* * * * *

(e) *Western Alaska CDQ Program.* The goals and purpose of the CDQ program are to allocate CDQ to eligible Western Alaska communities to provide the means for starting or supporting commercial fisheries business activities that will result in an ongoing, regionally-based, fisheries-related economy.

* * * * *

(j) *License Limitation Program.* (1) Regulations in this part implement the license limitation program for the commercial groundfish fisheries in the EEZ off Alaska and for the commercial crab fisheries for the Bering Sea and Aleutian Islands in the EEZ off Alaska.

(2) Regulations in this part govern the commercial fishing for license limitation groundfish by vessels of the United States using authorized gear within that portion of the Gulf of Alaska and the Bering Sea and Aleutian Islands management area over which the United States exercises exclusive fishery management authority and the commercial fishing for crab species by vessels of the United States using authorized gear within that portion of the Bering Sea and Aleutian Islands management area over which the United

States exercises exclusive fishery management authority.

3. In § 679.2, the definition for "Governor" is removed; the definitions for "Community Development Plan (CDP)", "Community Development Quota (CDQ)", "Legal Landing", "Maximum LOA", "Person", "Processing or to process", "Qualified Applicant", "Qualified Person", and "Resident Fisherman" are revised; and definitions for "Area Endorsement", "Area/Species Endorsement", "Catcher/Processor Vessel Designation", "Catcher Vessel Designation", "CDQ Allocation", "CDQ Fishing", "CDQ Group", "CDQ Number", "CDQ Project", "CDQ Representative", "CDQ Species", "Crab Species", "Crab Species License", paragraph (3) for "Directed Fishing", "Eligible Applicant", "Eligible Community", "Groundfish License", "License Holder", "License Limitation Groundfish", "Managing Organization", "Prohibited Species Quota", "PSQ Allocation", "PSQ Species", "State", and "Vessel Length Category" are added in alphabetical order to read as follows:

§ 679.2 Definitions.

Area endorsement means the designation(s) on a license that authorizes a license holder to conduct directed fishing for license limitation groundfish in the designated area(s), subarea(s), or district(s). Area endorsements, which are inclusive of, but not necessarily the same as, management areas, subareas, or districts defined in this part, are as follows:

- (1) Aleutian Islands area endorsement. Authorizes the license holder to conduct directed fishing for license limitation groundfish in the Aleutian Islands Subarea;
- (2) Bering Sea area endorsement. Authorizes the license holder to conduct directed fishing for license limitation groundfish in the Bering Sea Subarea;
- (3) Central Gulf area endorsement. Authorizes the license holder to conduct directed fishing for license limitation groundfish in the Central Area of the Gulf of Alaska and the West Yakutat District;
- (4) Southeast Outside area endorsement. Authorizes the license holder to conduct directed fishing for license limitation groundfish in the Southeast Outside District; and
- (5) Western Gulf area endorsement. Authorizes the license holder to conduct directed fishing for license limitation groundfish in the Western Area of the Gulf of Alaska.

Area/species endorsement means the designation(s) on a license that authorizes a license holder to conduct directed fishing for the designated crab

species in Federal waters in the designated area(s). Area/species endorsements for crab species licenses are as follows:

(1) Adak brown king in waters with an eastern boundary of 171° W. long., a western boundary of the U.S.-Russian Convention Line of 1867, and a northern boundary of 55°30' N. lat.

(2) Adak red king in waters with an eastern boundary of 171° W. long., a western boundary of the U.S.-Russian Convention Line of 1867, and a northern boundary of 55°30' N. lat.

(3) Bristol Bay red king in waters with a northern boundary of 58° 39' N. lat., a southern boundary of 54° 36' N. lat., and a western boundary of 168° W. long. and including all waters of Bristol Bay.

(4) BS/AI *C. opilio* and *C. bairdi* in Pacific Ocean waters with a northern boundary of 58° 52' N. lat., and an eastern boundary of 148° 50' W. long. and all Bering Sea and Pacific Ocean waters east of the U.S.-Russian Convention Line of 1867, excluding:

(i) Pacific Ocean waters with a northern boundary of 58° 52' N. lat., an eastern boundary of 148° 50' W. long., and a western boundary of 157° 27' W. long.

(ii) Pacific Ocean waters with an eastern boundary line from the southernmost tip of Kupreanof Point to the easternmost tip of Castle Rock and extending southeast (135°) from that easternmost point, and a western boundary line extending south (180°) from Scotch Cap Light.

(iii) Pacific Ocean waters with a western boundary line from the southernmost tip of Kupreanof Point to the easternmost tip of Castle Rock and extending southeast (135°) from that easternmost point, and an eastern boundary line of the longitude of the easternmost tip of Cape Kumlik.

(5) Dutch Harbor brown king in waters with a northern boundary of 54° 36' N. lat., an eastern boundary of the longitude of Scotch Cap Light, and a western boundary of 171° W. long., excluding the waters with a southern boundary line from 54° 36' N. lat., 168° W. long., to 54° 36' N. lat., 171° W. long., to 55° 30' N. lat., 171° W. long., to 55° 30' N. lat., 173° 30' E. lat., a northern boundary of 68° 21' N. lat., an eastern boundary line from 54° 36' N. lat., 168° W. long., to 58° 39' N. lat., 168° W. long., to 59° 39' N. lat., and a western boundary of the U.S.-Russian Convention line of 1867.

(6) Norton Sound red king and Norton Sound blue king in waters with a western boundary of 168° W. long., a southern boundary of 61° 49' N. lat., and a northern boundary of 65° 36' N. lat.

(7) Pribilof red king and Pribilof blue king in waters with a northern boundary

of 58° 39' N. lat., an eastern boundary of 168° W. long., a southern boundary line from 54° 36' N. lat., 168° W. long., to 54° 36' N. lat., 171° W. long., to 55° 30' N. lat., 171° W. long., to 55° 30' N. lat., 173° 30' E. lat., and a western boundary of the U.S.-Russian Convention line of 1867.

(8) St. Matthew blue king in waters with a northern boundary of 61° 49' N. lat., a southern boundary of 58° 39' N. lat., and a western boundary of the U.S.-Russian Convention line of 1867.

Catcher/processor vessel designation means a license designation that authorizes a license holder:

(1) To conduct directed fishing for license limitation groundfish and/or process license limitation groundfish on a vessel; or

(2) To conduct directed fishing for crab species and/or process crab species on a vessel.

Catcher vessel designation means a license designation that authorizes a license holder:

(1) To conduct directed fishing for, but not process, license limitation groundfish on a vessel; or

(2) To conduct directed fishing for, but not process, crab species on a vessel.

Community Development Plan (CDP) means a business plan for the economic and social development of a specific Western Alaska community or group of communities under the CDQ program at § 679.30.

Community Development Quota (CDQ) means the annual amount of a particular CDQ species, in metric tons or numbers of animals, that a CDQ group is permitted to catch based on a CDQ allocation that has been requested in a proposed CDP and approved by NMFS.

CDQ allocation means a percentage of a CDQ reserve, defined at § 679.31, which is assigned to a CDQ group when NMFS approves a proposed CDP.

CDQ fishing means fishing for any CDQ or PSQ species.

CDQ group means a qualified applicant with an effective CDP.

CDQ number means a number assigned to the CDQ group by NMFS that is to be used on all reports submitted by the CDQ group.

CDQ project means any program that is funded by a CDQ group's assets for the economic or social development of a community or group of communities that are participating in a CDQ group, including but not limited to, infrastructure development, CDQ investments, employment and training programs, and CDP administration.

CDQ representative means the individual who is the official contact for

NMFS regarding all matters relating to a CDQ group's activities.

CDQ species means any species or species group that has been assigned to a CDQ reserve as specified at § 679.31(b)–(f).

Crab species means all crab species covered by the Fishery Management Plan for the Commercial King and Tanner Crab Fisheries in the Bering Sea/Aleutian Islands, including, but not limited to, red king crab (*Paralithodes camtschatica*), blue king crab (*Paralithodes platypus*), brown or golden king crab (*Lithodes aequispina*), scarlet or deep sea king crab (*Lithodes couesi*), Tanner or bairdi crab (*Chionoecetes bairdi*), opilio or snow crab (*Chionoecetes opilio*), grooved Tanner crab (*Chionoecetes tanneri*), and triangle Tanner crab (*Chionoecetes angulatus*).

Crab species license means a license issued by NMFS that authorizes the vessel designated on the license to conduct directed fishing for crab species.

Directed fishing means:

* * * * *

(3) With respect to license limitation groundfish species, directed fishing as defined in paragraph (1) of this definition, or, with respect to license limitation crab species, the catching and retaining of any license limitation crab species.

Eligible applicant means:

(1) A qualified person who owned a vessel on June 17, 1995, that made legal landings of license limitation groundfish or crab species in the appropriate areas during the qualifying periods specified in § 679.4(i) (4) and (5), unless the fishing history of that vessel was transferred in conformance with the provisions in paragraph (2) of this definition; or

(2) A qualified person to whom the fishing history of a vessel that made legal landings of license limitation groundfish or crab species in the appropriate areas during the qualifying periods specified in § 679.4(i) (4) and (5) has been transferred by the express terms of a written contract that clearly and unambiguously provides that the qualifications for a license under the LLP have been transferred.

(3) Notwithstanding the provisions of paragraphs (1) and (2) of this definition, for purposes of eligibility for an area/species endorsement specified at § 679.4(i)(5)(ii)(H), an eligible applicant also includes (i) an individual who held a State of Alaska permit for the Norton Sound king crab summer fishery in 1993 and 1994, and who made at least one landing of red or blue king crab in the

appropriate area during the period specified in § 679.4(i)(5)(ii)(H), or (ii) a corporation that owned or leased a vessel on June 17, 1995, that made at least one landing of red or blue king crab in the appropriate area during the period in § 679.4(i)(5)(ii)(H), and that was operated by an individual who was an employee or a temporary contractor;

Eligible community means a community:

(1) That is located within 50 nm from the baseline from which the breadth of the territorial sea is measured along the Bering Sea coast from the Bering Strait to the most western of the Aleutian Islands, or on an island within the Bering Sea. A community is not eligible if it is located on the GOA coast of the North Pacific Ocean, even if it is within 50 nm of the baseline of the Bering Sea.

(2) That is certified by the Secretary of the Interior pursuant to the Native Claims Settlement Act (Pub. L. 92–203) to be a native village.

(3) Whose residents conduct more than half of their current commercial or subsistence fishing effort in the waters of the BSAI.

(4) That has not previously developed harvesting or processing capability sufficient to support substantial groundfish fisheries participation in the BSAI, unless the community can show that benefits from an approved CDP would be the only way to realize a return from previous investments. The community of Unalaska is excluded under this provision.

Groundfish license means a license issued by NMFS that authorizes a vessel to conduct directed fishing for license limitation groundfish.

Legal landing means a landing in compliance with Federal and state commercial fishing regulations in effect at the time of landing.

License holder means the person who received a groundfish or crab species license by initial issuance or transfer, or the individual designated to use that license to conduct directed fishing for license limitation groundfish or crab species by the person who received a groundfish or crab species license by initial issuance or transfer.

License limitation groundfish means target species and the "other species" category, specified annually pursuant to § 679.20(a)(2), except that demersal shelf rockfish east of 140° W. longitude and sablefish managed under the IFQ program are not considered license limitation groundfish.

Managing organization means the organization responsible for managing all or part of a CDP.

Maximum LOA (MLOA) means:

(1) (Applicable through December 31, 1998) with respect to a vessel's eligibility for a moratorium permit:

(i) Except for a vessel under reconstruction on June 24, 1992, if the original qualifying LOA is less than 125 ft (38.1 m) LOA, 1.2 times the original qualifying LOA or 125 ft (38.1 m), whichever is less.

(ii) Except for a vessel under reconstruction on June 24, 1992, if the original qualifying LOA is equal to or greater than 125 ft (38.1 m), the original qualifying LOA.

(iii) For an original qualifying vessel under reconstruction on June 24, 1992, the LOA on the date reconstruction was completed, provided that maximum LOA is certified under § 679.4(c)(9).

(2) With respect to the license limitation program, 1.2 times the LOA of the vessel on June 24, 1992, or if the vessel was under reconstruction on June 24, 1992, 1.2 times the LOA of the vessel on the date reconstruction was completed, except that the maximum LOA of a vessel cannot exceed:

(i) 59 ft (18.0 m) LOA, if the LOA of the vessel on June 17, 1995, or on the date reconstruction was completed, was less than 60 ft (18.3 m);

(ii) 124 ft (37.8 m) LOA, if the LOA of the vessel on June 17, 1995, or on the date reconstruction was completed, was less than 125 ft (38.1 m); or

(iii) The LOA of the vessel on June 17, 1995, or on the date reconstruction was completed, if that LOA was 125 ft (38.1 m) or greater.

Person means:

(1) For purposes of IFQ species and the CDQ program, any individual who is a citizen of the United States or any corporation, partnership, association, or other entity (or its successor-in-interest), regardless of whether organized or existing under the laws of any state, who is a U.S. citizen.

(2) (Applicable through December 31, 1998). For the purposes of the moratorium, any individual who is a citizen of the United States or any U.S. corporation, partnership, association, or other entity (or their successor-in-interest), whether or not organized or existing under the laws of any state.

Processing, or to *process*, means the preparation of, or to prepare, fish or crab to render it suitable for human consumption, industrial uses, or long-term storage, including but limited to cooking, canning, smoking, salting, drying, freezing, or rendering into meal or oil, but does not mean icing, bleeding, heading, or gutting.

Prohibited species quota (PSQ) means the annual amount of a prohibited species listed in § 679.21(b)(1), in metric tons or numbers, that a CDQ group is

permitted to catch based on an allocation of that species which has been approved by NMFS.

PSQ allocation means a percentage of a PSQ reserve specified pursuant to § 679.31(g) that is assigned to a CDQ group when NMFS approves a proposed CDP.

PSQ species means any species that has been assigned to a PSQ reserve as specified at § 679.31(g) for purposes of the CDQ program.

Qualified applicant means, for the purposes of the CDQ program:

(1) A local fishermen's organization that represents an eligible community, or group of eligible communities, that is incorporated under the laws of the State of Alaska, or under Federal law, and whose board of directors is composed of at least 75 percent resident fishermen of the community (or group of communities); or

(2) A local economic development organization that represents an eligible community or group of communities, and that is incorporated under the laws of the State of Alaska, or under Federal law, specifically for the purpose of designing and implementing a CDP, and that has a board of directors composed of at least 75 percent resident fishermen of the community (or group of communities).

Qualified person means:

(1) With respect to the IFQ program, see IFQ Management Measures at § 679.40(a)(2).

(2) With respect to the license limitation program, a person who was eligible on June 17, 1995, to document a fishing vessel under Chapter 121, Title 46, U.S.C.

Resident fisherman means an individual with documented commercial or subsistence fishing activity who maintains a mailing address and permanent domicile in the community and is eligible to receive an Alaska Permanent Fund dividend at that address.

State means the State of Alaska.

Vessel length category means the length category designated on a license based on the MLOA of the vessel.

4. In § 679.4, paragraph (e) is revised and paragraphs (a)(6) and (i) are added to read as follows:

§ 679.4 Permits.

(a) * * *

(6) *Harvesting privilege*. Quota shares, permits, or licenses issued pursuant to this part are neither an absolute right to the resource nor any interest that is subject to the "takings" provision of the Fifth Amendment to the U.S. Constitution. Rather, such quota shares, permits, or licenses represent only a

harvesting privilege that may be revoked or amended subject to the requirements of the Magnuson-Stevens Act and other applicable law.

* * * * *

(e) *CDQ permit*—(1) *Applicability*. This paragraph applies to vessels or processors required in § 679.32 to obtain a CDQ permit prior to harvesting or taking deliveries of CDQ catch.

(2) *Application for a permit*. A complete application for a CDQ permit must include the following:

(i) The name and signature of the person submitting the application and the date the application was signed.

(ii) The year for which the CDQ permit is requested.

(iii) Whether the vessel or processor has received a CDQ permit before and, if so, the most recent year.

(iv) The vessel or processor name.

(v) The Federal fishery or processor permit number.

(vi) The street address, mailing address, telephone number, and fax number of the person submitting the application.

(vii) And for the following types of vessels or processors:

(A) *Trawl catcher/processors and motherships*.

(1) A diagram drawn to scale showing the location(s) where all CDQ and PSQ will be weighed on a certified scale, the location where observers will sample unsorted catch, and the location of the observer sampling station as described at § 679.28(d), including the observer sampling scale.

(2) The name of the manufacturer and model of the motion-compensated observer sampling scale.

(3) A copy of the most recent at-sea scale inspection certificate.

(B) *Shoreside processing plants*. A diagram drawn to scale showing the location(s) where all CDQ and PSQ will be sorted and weighed on a scale certified by the State of Alaska.

(C) *Longline and pot catcher/processors and catcher vessels*. The name of manufacturer and model of the motion-compensated observer sampling scale.

(3) *Issuance of permit*. A CDQ permit will be issued to the applicant when the following requirements are met:

(i) The Regional Administrator receives a completed CDQ permit application.

(ii) NMFS completes an inspection of the vessel or processor and verifies that the following requirements are met.

(A) The scale(s) on trawl catcher/processors or motherships to weigh CDQ catch have been certified by an authorized weights and measures

agency within twelve months of the date of inspection.

(B) The scale on a trawl catcher/processor or mothership is located so that an observer can sample unsorted catch after it has been weighed on the scale.

(C) The observer sampling station on a vessel meets the requirements of § 679.28(d).

(D) The scale or scales in a shoreside processing plant meet the requirements of § 679.28(c) and the CDQ observer can monitor the sorting and weighing of all CDQ species.

(4) *Duration*. CDQ permits are effective the calendar year requested by the applicant. Issuance of a CDQ permit means that the vessel or processor complied with the requirements in paragraph (e)(3) of this section on the date the vessel or processor was inspected. Once permitted, vessel and processor owners and operators also are responsible for complying with all equipment and operational requirements in § 679.28 and § 679.32.

* * * * *

(i) *Licenses for license limitation groundfish or crab species*—(1) *General requirements*. (i) In addition to the permit and licensing requirements prescribed in this part, and except as provided in paragraph (i)(2) of this section, each vessel within that portion of the Gulf of Alaska and the Bering Sea and Aleutian Islands management area over which the United States exercises exclusive fishery management authority must have a groundfish license on board at all times it is engaged in fishing activities defined in § 679.2 as directed fishing for license limitation groundfish. This groundfish license, issued by NMFS to a qualified person, authorizes a license holder to conduct directed fishing for license limitation groundfish only in the specific area(s) designated on the license and may only be used on a vessel that complies with the vessel designation and vessel length category specified on the license.

(ii) In addition to the permit and licensing requirements prescribed in this part, and except as provided in paragraph (i)(2) of this section, each vessel within that portion of the Bering Sea and Aleutian Islands area over which the United States exercises exclusive fishery management authority must have a crab species license on board at all times it is engaged in fishing activities defined in § 679.2 as directed fishing for crab species. This crab species license, issued by NMFS to a qualified person, authorizes a license holder to conduct directed fishing for crab species only for the specific species

and in the specific area(s) designated on the license, and may only be used on a vessel that complies with the vessel designation and vessel length category specified on the license.

(2) *Exempt vessels.* Notwithstanding the requirements of paragraph (i)(1) of this section,

(i) A catcher vessel or catcher/processor vessel that does not exceed 26 ft (7.9 m) LOA may conduct directed fishing for license limitation groundfish in the Gulf of Alaska without a groundfish license;

(ii) A catcher vessel or catcher/processor vessel that does not exceed 32 ft (9.8 m) LOA may conduct directed fishing for crab species in the Bering Sea and Aleutian Islands management area and also may conduct directed fishing for license limitation groundfish in the Bering Sea and Aleutian Islands management area without a groundfish or crab species license;

(iii) A catcher vessel or catcher/processor vessel that does not exceed 60 ft (18.3 m) LOA may use a maximum of 5 jig machines, one line per jig machine, and a maximum of 15 hooks per line, to conduct directed fishing for license limitation groundfish in the Bering Sea and Aleutian Islands management area without a groundfish license; or

(iv) A catcher vessel or catcher/processor vessel that does not exceed 125 ft (38.1 m) LOA, and that was, after November 18, 1992, specifically constructed for and used exclusively in accordance with a CDQ approved by the Secretary of Commerce under subpart C of this part, and is designed and equipped to meet specific needs that are described in the CDQ.

(3) *Vessel designations and vessel length categories*—(i) *General.* A license can be used only on a vessel that complies with the vessel designation specified on the license and that has an LOA less than or equal to the MLOA specified on the license.

(ii) *Vessel designations*—(A) *Catcher vessel.* A license will be assigned the vessel designation of catcher vessel if:

(1) For license limitation groundfish, no license limitation groundfish were processed on the vessel that qualified for the groundfish license under paragraph (i)(4) of this section during the period January 1, 1994, through June 17, 1995, or in the most recent calendar year of participation during the area endorsement qualifying period specified in paragraph (i)(4)(ii) of this section; or

(2) For crab species, no crab species were processed on the vessel that qualified for the crab species license under paragraph (i)(5) of this section during the period January 1, 1994, through December 31, 1994, or in the

most recent calendar year of participation during the area/species endorsement qualifying period specified in paragraph (i)(5)(ii) of this section.

(B) *Catcher/processor vessel.* A license will be assigned the vessel designation of catcher/processor vessel if:

(1) For license limitation groundfish, license limitation groundfish were processed on the vessel that qualified for the groundfish license under paragraph (i)(4) of this section during the period January 1, 1994, through June 17, 1995, or in the most recent calendar year of participation during the area endorsement qualifying period specified in paragraph (i)(4)(ii) of this section; or

(2) For crab species, crab species were processed on the vessel that qualified for the crab species license under paragraph (i)(5) of this section during the period January 1, 1994, through December 31, 1994, or in the most recent calendar year of participation during the area endorsement qualifying period specified in paragraph (i)(5)(ii) of this section.

(C) *Changing a vessel designation.* A person who holds a groundfish license or a crab species license with a catcher/processor vessel designation may, upon request to the Regional Administrator, have the license reissued with a catcher vessel designation. The vessel designation change to a catcher vessel will be permanent and that license will be valid for only those activities specified in the definition of catcher vessel designation at § 679.2.

(iii) *Vessel length categories.* A license will be assigned one of the following three vessel length categories based on its LOA on June 17, 1995:

(A) Vessel length category "A" if the LOA of the qualifying vessel on June 17, 1995, was equal to or greater than 125 ft (38.1 m) LOA.

(B) Vessel length category "B" if the LOA of the qualifying vessel on June 17, 1995, was equal to or greater than 60 ft (18.3 m) but less than 125 ft (38.1 m) LOA.

(C) Vessel length category "C" if the LOA of the qualifying vessel on June 17, 1995, was less than 60 ft (18.3 m) LOA.

(4) *Qualifications for a groundfish license.* A groundfish license will be issued to an eligible applicant who owned a vessel that meets the criteria in paragraphs (i)(4)(i) and (i)(4)(ii) of this section.

(i) *General qualification periods (GQP).* (A) To qualify for one or more of the area endorsements in paragraphs (i)(4)(ii)(A) and (i)(4)(ii)(B) of this section, a vessel must have made at least one legal landing of any amount of license limitation groundfish species

harvested in the Bering Sea and Aleutian Islands management area or in State waters shoreward of that management area from:

(1) January 1, 1988, through June 27, 1992;

(2) January 1, 1988, through December 31, 1994, provided that the landing was of license limitation groundfish harvested using pot or jig gear from a vessel that was less than 60 ft (18.3 m) LOA; or

(3) January 1, 1988, through June 17, 1995, provided that the vessel qualified for a crab fisheries endorsement under the Moratorium on Entry.

(B) To qualify for one or more of the area endorsements in paragraphs (i)(4)(ii)(C) through (i)(4)(ii)(E) of this section, a vessel must have made at least one legal landing of any amount of license limitation groundfish species harvested in the Gulf of Alaska or in State waters shoreward of the Gulf of Alaska from:

(1) January 1, 1988, through June 27, 1992;

(2) January 1, 1988, through December 31, 1994, provided that the landing was of license limitation groundfish harvested using pot or jig gear from a vessel that was less than 60 ft (18.3 m) LOA; or

(3) January 1, 1988, through June 17, 1995, provided that the vessel qualified for a crab fisheries endorsement under the Moratorium on Entry.

(ii) *Endorsement qualification periods (EQP).* A groundfish license will be assigned one or more area endorsements based on the criteria in paragraphs (i)(4)(ii)(A) through (i)(4)(ii)(E) of this section.

(A) *Aleutian Islands area endorsement.* A vessel of any length (vessel categories "A" through "C") must have made at least one legal landing of any amount of license limitation groundfish harvested from January 1, 1992, through June 17, 1995, in the Aleutian Islands Subarea or in State waters shoreward of that subarea for an Aleutian Islands area endorsement.

(B) *Bering Sea area endorsement.* A vessel of any length (vessel categories "A" through "C") must have made at least one legal landing of any amount of license limitation groundfish harvested from January 1, 1992, through June 17, 1995, in the Bering Sea Subarea or in State waters shoreward of that subarea for a Bering Sea area endorsement.

(C) *Central Gulf area endorsement.* (1) A vessel assigned to vessel category "A" must have made at least one legal landing of any amount of license limitation groundfish harvested in each of any 2 calendar years from January 1,

1992, through June 17, 1995, in the Central Area of the Gulf of Alaska or in State waters shoreward of that area, or in the West Yakutat District or in state waters shoreward of that district, for a Central Gulf area endorsement.

(2) A vessel assigned to vessel category "B" must have made at least one legal landing of any amount of license limitation groundfish harvested in each of any 2 calendar years from January 1, 1992, through June 17, 1995, or at least four legal landings of license limitation groundfish harvested from January 1, 1995, through June 17, 1995, in the Central Area of the Gulf of Alaska or in State waters shoreward of that area, or in the West Yakutat District or in State waters shoreward of that district, for a Central Gulf area endorsement.

(3) A vessel assigned to vessel category "C" must have made at least one legal landing of any amount of license limitation groundfish harvested from January 1, 1992, through June 17, 1995, in the Central Area of the Gulf of Alaska or in State waters shoreward of that area, or in the West Yakutat District or in state waters shoreward of that district, for a Central Gulf area endorsement.

(D) *Southeast Outside area endorsement.* (1) A vessel assigned to vessel category "A" must have made at least one legal landing of any amount of license limitation groundfish harvested in each of any 2 calendar years from January 1, 1992, through June 17, 1995, in the Southeast Outside District or in State waters shoreward of that district for a Southeast Outside area endorsement.

(2) A vessel assigned to vessel category "B" must have made at least one legal landing of any amount of license limitation groundfish harvested in each of any 2 calendar years from January 1, 1992, through June 17, 1995, in the Southeast Outside District or in State waters shoreward of that district, or at least four legal landings of license limitation groundfish harvested from January 1, 1995, through June 17, 1995, in the Southeast Outside District or in State waters shoreward of that district for a Southeast Outside area endorsement.

(3) A vessel assigned to vessel category "C" must have made at least one legal landing of any amount of license limitation groundfish harvested from January 1, 1992, through June 17, 1995, in the Southeast Outside District or in State waters shoreward of that district for a Southeast Outside area endorsement.

(E) *Western Gulf area endorsement.* (1) A vessel assigned to vessel category

"A" must have made at least one legal landing of any amount of license limitation groundfish harvested in each of any 2 calendar years from January 1, 1992, through June 17, 1995, in the Western Area of the Gulf of Alaska or in State waters shoreward of that area for a Western Gulf area endorsement.

(2) A vessel assigned to vessel category "B" and the vessel designation of catcher vessel must have made at least one legal landing of any amount of license limitation groundfish harvested from January 1, 1992, through June 17, 1995, in the Western Area of the Gulf of Alaska or in State waters shoreward of that area for a Western Gulf area endorsement.

(3) A vessel assigned to vessel category "B" and the vessel designation of catcher/processor vessel must have made at least one legal landing of any amount of license limitation groundfish harvested in each of any 2 calendar years from January 1, 1992, through June 17, 1995, in the Western Area of the Gulf of Alaska or in State waters shoreward of that area, or at least four legal landings of any amount of license limitation groundfish harvested from January 1, 1995, through June 17, 1995, in the Western Area of the Gulf of Alaska or in State waters shoreward of that area for a Western Gulf area endorsement.

(4) A vessel assigned to vessel category "C" must have made at least one legal landing of any amount of license limitation groundfish harvested from January 1, 1992, through June 17, 1995, in the Western Area of the Gulf of Alaska or in State waters shoreward of that area for a Western Gulf area endorsement.

(iii) An eligible applicant that is issued a groundfish license based on a vessel's qualifications under paragraph (i)(4)(i)(A)(2) or (i)(4)(i)(B)(2) of this section must choose only one area endorsement for that groundfish license even if the vessel qualifies for more than one area endorsement.

(iv) Notwithstanding the provisions in paragraph (i)(4) of this section, an eligible applicant whose vessel made a legal landing of any amount of license limitation groundfish harvested in the Bering Sea and Aleutian Islands management area or in State waters shoreward of that management area during the GQP defined in paragraph (i)(4)(i)(A) of this section, and made legal landings of any amount of license limitation groundfish harvested in one of the areas of the Gulf of Alaska or in State waters shoreward of one of the areas of the Gulf of Alaska during the EQP defined in paragraphs (i)(4)(ii) (C), (D), and (E) of this section, but did not

make legal landings of any amount of license limitation groundfish harvested in the Gulf of Alaska or in State waters shoreward of the Gulf of Alaska during the GQP defined in paragraph (i)(4)(i)(B) of this section, and did not make legal landings of any amount of license limitation groundfish harvested in one of the areas of the Bering Sea and Aleutian Islands management area or in State waters shoreward of one of the areas of that management area during the EQP defined in paragraphs (i)(4)(ii) (A) and (B) of this section, will be issued a license with area endorsements based on the legal landings of license limitation groundfish harvested during the EQP and meeting the requirements in paragraphs (i)(4)(ii) (C), (D), and (E) of this section.

(v) Notwithstanding the provisions in paragraph (i)(4) of this section, an eligible applicant whose vessel made a legal landing of any amount of license limitation groundfish harvested in the Gulf of Alaska or in State waters shoreward of the Gulf of Alaska during the GQP defined in paragraph (i)(4)(i)(B) of this section, and made legal landings of any amount of license limitation groundfish harvested in one of the areas of the Bering Sea and Aleutian Islands management area or in State waters shoreward of one of the areas of that management area during the EQP defined in paragraphs (i)(4)(ii) (A) and (B) of this section, but did not make legal landings of any amount of license limitation groundfish harvested in the Bering Sea and Aleutian Islands management area or in State waters shoreward of that management area during the GQP defined in paragraph (i)(4)(i)(A) of this section, and did not make legal landings of license limitation groundfish harvested in one of the areas of the Gulf of Alaska or in State waters shoreward of one of the areas of the Gulf of Alaska during the EQP defined in paragraph (i)(4)(ii) (C), (D), and (E) of this section, will be issued a license with area endorsements based on the legal landings of license limitation groundfish harvested during the EQP and meeting the requirements in paragraphs (i)(4)(ii) (A) and (B) of this section.

(5) *Qualifications for a crab species license.* A crab species license will be issued to an eligible applicant who owned a vessel that meets the criteria in paragraphs (i)(5) (i) and (ii) of this section, except that vessels are exempt from the requirements in paragraph (i)(5)(i) of this section for the area/species endorsements in paragraph (i)(5)(ii) (A) and (H) of this section.

(i) *General qualification period (GQP).* To qualify for one or more of the area/

species endorsements in paragraph (i)(5)(ii) of this section, a vessel must have:

(A) Made at least one legal landing of any amount of crab species harvested from January 1, 1988, through June 27, 1992; or

(B) Made at least one legal landing of any amount of crab species harvested from January 1, 1988, through December 31, 1994, providing that the vessel qualified for a groundfish fisheries endorsement under the Moratorium on Entry.

(ii) *Area/Species Endorsements.* A crab species license will be assigned one or more area/species endorsements specified at § 679.2 based on the criteria in paragraphs (i)(5)(ii) (A) through (H) of this section.

(A) *Pribilof red king and Pribilof blue king.* A vessel must have made at least one legal landing of any amount of red king or blue king crab harvested in the area described in the definition for the Pribilof red king and Pribilof blue king area/species endorsement in § 679.2 from January 1, 1993, through December 31, 1994, to qualify for a Pribilof red king and Pribilof blue king area/species endorsement.

(B) *BS/AI C. opilio and C. bairdi.* A vessel must have made at least three legal landings of any amount of *C. opilio* or *C. bairdi* crab harvested in the area described in the definition for the BS/AI *C. opilio* or *C. bairdi* area/species endorsement in § 679.2 from January 1, 1992, through December 31, 1994, to qualify for a *C. opilio* and *C. bairdi* area/species endorsement.

(C) *St. Matthew blue king.* A vessel must have made at least one legal landing of any amount of blue king crab harvested in the area described in the definition for the St. Matthews blue king area/species endorsement in § 679.2 from January 1, 1992, through December 31, 1994, to qualify for a St. Matthew blue king area/species endorsement.

(D) *Adak brown king.* A vessel must have made at least three legal landings of any amount of brown king crab harvested in the area described in the definition for the Adak brown king area/species endorsement in § 679.2 from January 1, 1992, through December 31, 1994, to qualify for a Adak brown king area/species endorsement.

(E) *Adak red king.* A vessel must have made at least one legal landing of any amount of red king crab harvested in the area described in the definition for the Adak red king area/species endorsement in § 679.2 from January 1, 1992, through December 31, 1994, to qualify for a Adak red king area/species endorsement.

(F) *Bristol Bay red king.* A vessel must have made at least one legal landing of any amount of red king crab harvested in the area described in the definition for the Bristol Bay red king area/species endorsement in § 679.2 from January 1, 1991, through December 31, 1994, to qualify for a Bristol Bay red king area/species endorsement.

(G) *Dutch Harbor brown king.* A vessel must have made at least three legal landings of any amount of brown king crab harvested in the area described in the definition for the Dutch Harbor brown king area/species endorsement in § 679.2 from January 1, 1992, through December 31, 1994, to qualify for a Dutch Harbor brown king area/species endorsement.

(H) *Norton Sound red king and Norton Sound blue king.* A vessel must have made at least one legal landing of any amount of red king or blue king crab harvested in the area described in the definition for the Norton Sound red king and Norton Sound blue king area/species endorsement in § 679.2 from January 1, 1993, through December 31, 1994, to qualify for a Norton Sound red king and Norton Sound blue king area/species endorsement.

(6) *Application for a groundfish license or a crab species license.* (i) An eligible applicant must meet all the criteria for eligibility in paragraph (i) of this section and submit a complete application to the Regional Administrator to receive a groundfish license or a crab species license.

(ii) A successor-in-interest may apply in the place of an eligible applicant if the eligible applicant is unable to apply for a license because:

(A) Of death or disability at the time of application, if the eligible applicant is an individual; or

(B) The entity is no longer in existence at the time of application, if the eligible applicant is not an individual.

(iii) An application for a groundfish license or a crab species license may be requested from and submitted to the Restricted Access Management Division, Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802-1668. An application may be requested also by telephone by calling 907-586-7202 or 800-304-4846 or by facsimile by calling 907-586-7354. To be complete, an application for a groundfish license or a crab species license must be signed by the eligible applicant, or the person who represents the eligible applicant, and include:

(A) The name of the vessel, state registration number of the vessels and, the U.S. Coast Guard documentation number of the vessel, if any.

(B) The name, business address, and telephone and fax number of the owner of the vessel as of June 17, 1995, including all owners if more than one.

(C) The name of the managing company.

(D) Valid documentation of the legal landings that qualify the vessel for a groundfish license or a crab species license if requested by the Regional Administrator due to an absence of landing records for the vessel during the qualifying periods.

(E) Valid documentation of the vessel's LOA on June 17, 1995. For purposes of determining LOA for the License Limitation Program, an eligible applicant must provide evidence showing:

(1) The vessel's length on June 24, 1992, or the vessel's length on the date reconstruction was completed if the vessel was being reconstructed on June 24, 1992;

(2) The vessel's length on June 17, 1995; and

(3) The date the vessel was lengthened and the vessel's length before and after that date, if the vessel was lengthened after June 24, 1992.

(F) Valid documentation to support the vessel's designation of catcher vessel or catcher/processor vessel based on the criteria in § 679.4(i)(3)(i).

(7) *Transfers*—(i) *General.* A license holder may request NMFS, on a transfer request form provided by NMFS, to transfer the license to a transferee designated by the license holder on the transfer request form. The designated transferee may not conduct directed fishing for license limitation groundfish or crab species until NMFS reissues the license in the name of the designated transferee.

(ii) *Reissuance procedures.* A license holder who wishes to transfer the license to another person must request NMFS to reissue the license to that person by submitting a complete transfer request form to NMFS to the address specified in paragraph (i)(6)(ii) of this section. Forms are available from that address.

(A) To be complete, a transfer request form must be signed and dated by the license holder and include:

(1) The name of the license holder (the names of all persons holding the license must be included if more than one person holds the license);

(2) The name of the person who is the designated transferee and to whom the license is to be reissued (the names of all persons who are the designated transferee must be included if more than one person is the designated transferee);

(3) Valid documentation that the designated transferee(s) is or are able to

document a fishing vessel under Chapter 121, Title 46, U.S.C.

(B) The Regional Administrator shall reissue the license to the designated transferee if:

(1) A complete transfer request has been submitted by the transferor.

(2) The designated transferee is a person able to document a fishing vessel under Chapter 121, Title 46, U.S.C..

(3) There are no fines, civil penalties, other payments due and outstanding, or outstanding permit sanctions resulting from Federal fishing violations involving any party to the transfer.

(4) The transfer will not cause the designated transferee to exceed the license caps in § 679.7(i).

(iii) *Severability of licenses.* (A) Area endorsements or area/species endorsements specified on a license are not severable from the license and must be transferred together.

(B) A groundfish license and a crab species license issued based on the legal landings of the same vessel and initially issued to the same qualified person are not severable and must be transferred together.

(8) *Other provisions.* (i) Any person committing, or a fishing vessel used in the commission of, a violation of the Magnuson-Stevens Fishery Conservation and Management Act or any regulations issued pursuant thereto, is subject to the civil and criminal penalty provisions and the civil forfeiture provisions of the Magnuson-Stevens Fishery Conservation and Management Act, part 621 of this chapter, 15 CFR part 904 (Civil Procedure), and other applicable law. Penalties include, but are not limited to, permanent or temporary sanctions to licenses.

(ii) Notwithstanding the provisions of the license limitation program in this part, vessels fishing for species other than license limitation groundfish as defined in § 679.2 that were authorized under Federal regulations to incidentally catch license limitation groundfish without a Federal fisheries permit described at § 679.4(b) will continue to be authorized to catch the maximum retainable bycatch amounts of license limitation groundfish as provided in this part without a groundfish license.

(iii) An eligible applicant, who qualifies for a groundfish license or crab species license but whose vessel has been subsequently lost or destroyed, will be issued the license for which the lost or destroyed vessel qualified. This license:

(A) Will have the vessel designation and vessel length category of the lost or destroyed vessel.

(B) Cannot be used to conduct directed fishing for license limitation groundfish or to conduct directed fishing for crab species on a vessel that has an LOA greater than the MLOA designated on the license.

(iv) A qualified person who owned a vessel on June 17, 1995, that made a legal landing of license limitation groundfish, or crab species if applicable, between January 1, 1988, and February 9, 1992, but whose vessel was unable to meet all the criteria in paragraph (i)(4) of this section for a groundfish license or paragraph (i)(5) of this section for a crab species license because of an unavoidable circumstance (i.e., the vessel was lost, damaged, or otherwise unable to participate in the license limitation groundfish or crab fisheries) may receive a license if the qualified person is able to demonstrate:

(A) That the owner of the vessel at the time of the unavoidable circumstance held a specific intent to conduct directed fishing for license limitation groundfish or crab species with that vessel during a specific time period in a specific area.

(B) That the specific intent to conduct directed fishing for license limitation groundfish or crab species with that vessel was thwarted by a circumstance that was:

(1) Unavoidable.

(2) Unique to the owner of that vessel, or unique to that vessel.

(3) Unforeseen and reasonably unforeseeable to the owner of the vessel.

(C) That the circumstance that prevented the owner from conducting directed fishing for license limitation groundfish or crab species actually occurred.

(D) That, under the circumstances, the owner of the vessel took all reasonable steps to overcome the circumstance that prevented the owner from conducting directed fishing for license limitation groundfish or crab species.

(E) That any amount of license limitation groundfish or appropriate crab species was harvested on the vessel in the specific area that corresponds to the area endorsement or area/species endorsement for which the qualified person who owned a vessel on June 17, 1995, is applying and the harvested license limitation groundfish or crab species was legally landed after the vessel was prevented from participating by the unavoidable circumstance but before June 17, 1995.

(v) A groundfish license or a crab species license may be used on a vessel that complies with the vessel designation on the license and that does not exceed the MLOA on the license.

5. In § 679.5, new paragraphs (m) and (n) are added to read as follows:

§ 679.5 Recordkeeping and reporting.

* * * * *

(m) *CDQ check-in/check-out report.*

The CDQ representative must submit a check-in/check-out report for each vessel harvesting groundfish and halibut CDQ under Subpart C of this part.

(1) *Check-in.* The CDQ representative must submit a check-in message by fax to NMFS before the operator of a catcher vessel or catcher/processor begins harvesting groundfish or halibut CDQ. The check-in message must be submitted before the first trip of the year and if CDQ fishing begins again after a check-out message has been sent for the vessel.

(2) *Check-out.* The CDQ representative must submit a check-out message by fax to NMFS after the delivery of CDQ catch by a catcher vessel unless that vessel will be CDQ fishing on its next trip and after the retrieval of a CDQ haul or set by a catcher/processor unless that vessel will be CDQ fishing on its next haul or set. The check-out message must be received by NMFS before the vessel deploys gear in a non-CDQ fishery.

(3) *Information required.* The CDQ representative must include the following in each CDQ check-in/check-out report.

(i) The CDQ number.

(ii) The vessel name.

(iii) The Federal fisheries or processor number or ADF&G number if the vessel is not required to have a Federal fisheries permit.

(iv) *Check-in message—(A) Catcher vessel.* The date the CDQ trip will start.

(B) *Catcher/processor.* The date CDQ fishing will start and the first haul or set number for the CDQ catch.

(v) *Check-out message—(A) Catcher vessel.* The date CDQ catch was delivered and name of processor that received delivery.

(B) *Catcher/processor.* The date CDQ fishing ended and the last haul or set number for the CDQ catch.

(vi) The CDQ representative's printed name and signature, and the date of signature.

(n) *CDQ catch report—(1) Applicability.* The CDQ representative must submit a catch report summarizing the CDQ and PSQ catch for each vessel each week that CDQ fishing occurs.

(2) *Time limits and submittal.* The CDQ representative must submit a CDQ catch report to NMFS no later than 1200 hours, A.L.T., on the Tuesday following the end of the applicable weekly reporting period.

(3) *Information required.* The CDQ representative must include the following in each CDQ catch report.

(i) Whether the submission is an original or revised report.

(ii) The CDQ number.

(iii) The week ending date.

(iv) *CDQ and PSQ catch information.* The CDQ representative must report the following CDQ and PSQ catch information for each catcher/processor harvesting and each catcher vessel delivering CDQ or PSQ during the weekly reporting period.

(A) The Federal fisheries or processor number or ADF&G number if the vessel is not required to have a Federal fisheries permit.

(B) The vessel name.

(C) The gear type used to harvest CDQ.

(D) The total weight to the nearest 0.01 mt or the total number of catch of all species in each category of CDQ or PSQ. The catch of nonallocated species from any vessel; the catch of crab, herring, or salmon PSQ from non-trawl vessels; or the catch of halibut PSQ from vessels using pot gear should not be reported on the CDQ catch report.

(v) The CDQ representative's printed name, signature, and date of signature.

6. In § 679.7, paragraph (d) is revised and paragraph (j) is added to read as follows:

§ 679.7 Prohibitions.

* * * * *

(d) *CDQ.* (1) Participate in a Western Alaska CDQ program in violation of subpart C of this part.

(2) Fail to submit, submit inaccurate information on, or intentionally submit false information on any report, application, or statement required under this part.

(3) Participate as a community in more than one CDP unless the second CDP is for a halibut CDQ fishery only.

(4) Harvest groundfish or halibut CDQ or PSQ on behalf of a CDQ group if the vessel is not listed as an eligible vessel on an approved CDP, before the CDQ representative has submitted a check-in report for the vessel, or after the CDQ representative has submitted a check-out report for the vessel.

(5) For a catcher/processor or shoreside processor, catch or take delivery of CDQ without a valid CDQ permit.

(6) For a CDQ group, exceed a CDQ or halibut PSQ.

(7) Use trawl gear to harvest groundfish CDQ in Zone 1 after the CDQ group's red king crab PSQ or *C. bairdi* Tanner crab PSQ in Zone 1 is attained.

(8) Use trawl gear to harvest groundfish CDQ in Zone 2 after the CDQ

group's PSQ for *C. bairdi* Tanner crab in Zone 2 is attained.

(9) Use trawl gear to harvest groundfish CDQ in Herring Savings Areas (HSA) after the CDQ group's herring PSQ is attained.

(10) Use trawl gear to harvest groundfish CDQ in the Chinook Salmon Savings Area between January 1 and April 15 after the CDQ group's chinook salmon PSQ is attained.

(11) Use trawl gear to harvest groundfish CDQ in the Chum Salmon Savings Area between September 1 and October 14 after the CDQ group's non-chinook salmon PSQ is attained.

(12) For a vessel operator, harvest CDQ fixed gear sablefish or halibut with other than fixed gear.

(13) For a catcher vessel using trawl gear, discard any groundfish CDQ species or salmon or herring PSQ before it is delivered to an eligible processor under a CDP.

(14) For a vessel using trawl gear, release CDQ catch from the codend before it is brought onboard the vessel and weighed on a certified scale. This includes, but is not limited to, "codend dumping" and "codend bleeding."

(15) For a catcher vessel, catch, retain on board, or deliver CDQ groundfish or halibut together with non-CDQ groundfish or halibut, except that IFQ sablefish and halibut may be caught, retained, or delivered together with CDQ groundfish and halibut by vessels using fixed gear.

(16) For a catcher/processor or an observed catcher vessel, combine catch from more than one CDQ group or from CDQ and IFQ in the same haul or set.

(17) Use any CDQ groundfish as a basis species for calculating retainable bycatch amounts under § 679.20.

(18) For a CDQ representative, use methods other than those approved in the CDP to report CDQ and PSQ on the CDQ catch report.

(19) Fail to comply with the requirements of a CDP.

* * * * *

(j) *License Limitation Program*—(1) *Number of licenses.* (i) Hold more than ten groundfish licenses in the name of that person at any time, except as provided in paragraph (i)(1)(iii) of this section;

(ii) Hold more than five crab species licenses in the name of that person at any time, except as provided in paragraph (i)(1)(iii) of this section; or

(iii) Hold more licenses than allowed in paragraphs (i)(1) (i) and (ii) of this section unless those licenses were issued to that person in the initial distribution of licenses. Any person who receives in the initial distribution

more licenses than allowed in paragraphs (i)(1) (i) and (ii) of this section shall have no transfer applications for receipt of additional licenses approved until the number of licenses in the name of that person is less than the numbers specified in paragraphs (i)(1) (i) and (ii) of this section; furthermore, when a person becomes eligible to receive licenses by transfer through the provisions of this paragraph, that person is subject to the provisions in paragraphs (i)(1) (i) and (ii) of this section;

(2) Use gear other than fixed gear east of 140° W. long., regardless of the gear used to qualify for the license;

(3) Conduct directed fishing for license limitation groundfish without a groundfish license, except as provided in § 679.4(i)(2);

(4) Conduct directed fishing for crab species without a crab species license, except as provided in § 679.4(i)(2);

(5) Process license limitation groundfish on board a vessel without a groundfish license with a Catcher/processor designation;

(6) Process crab species on board a vessel without a crab species license with a Catcher/processor designation;

(7) Use a license on a vessel that has an LOA that exceeds the MLOA of the vessel that was used to originally qualify for that license;

(8) Lease a groundfish or crab species license.

7. In § 679.20, paragraphs (c)(1)(iii), (c)(2)(ii), and (c)(3)(iii) are revised, and paragraph (e)(3) is added to read as follows:

§ 679.20 General limitations.

* * * * *

(c) *Annual Specifications*—(1) *Proposed specifications*—* * *

(iii) *BSAI.* The BSAI proposed specifications will specify the annual TAC and initial TAC amounts for each target species and the "other species" category and apportionments thereof established under § 679.20(a)(2), prohibited species catch allowances established under § 679.21, seasonal allowances of pollock TAC (including pollock CDQ), and reserve amounts established under § 679.31 (b), (d), (e), and (g) for pollock CDQ, sablefish CDQ, groundfish CDQ, and PSQ.

(2) *Interim specifications.* * * *

(ii) *BSAI.* Except for pollock and the hook and line and pot gear allocation of sablefish, one quarter of each proposed initial TAC and apportionment thereof, one quarter of each CDQ reserve established under § 679.31 (b), (d), (e), and (g), and one quarter of the proposed prohibited species catch allowance established under § 679.21.

(A) The interim specifications for pollock will be equal to the first seasonal allowance under paragraph (a)(5)(i)(A) of this section that is published in the proposed specifications under paragraph (c)(1) of this section.

(B) The interim specifications for CDQ pollock will be equal to the first seasonal allowance that is published in the proposed specifications under paragraph (c)(1) of this section.

(3) *Final specifications.* * * *

(iii) The final specifications will specify the annual TAC for each target species and the "other species" category and apportionments thereof, prohibited species catch allowances, seasonal allowances of the pollock TAC (including pollock CDQ), and the reserve amounts established under § 679.31 (b), (d), (e) and (g) for pollock CDQ, sablefish CDQ, groundfish CDQ, and PSQ, respectively.

* * * * *

(e) * * *

(3) *CDQ.* Retained CDQ species may not be used as a basis species to calculate maximum retainable bycatch amounts.

* * * * *

8. In § 679.21, paragraphs (b)(2)(ii), (b)(3), (e)(1) (v) and (vi) are revised, and paragraphs (e)(3)(iv)(G) and (e)(4)(ii)(F) are added to read as follows:

§ 679.21 Prohibited species bycatch management.

* * * * *

(b) * * *

(2) * * *

(ii) Sort its catch immediately after retrieval of the gear and, except as provided below, return all prohibited species or parts thereof to the sea immediately, with a minimum of injury, regardless of its condition, after allowing for sampling by an observer if an observer is aboard. The following exceptions are made.

(A) Salmon prohibited species catch in the BSAI non-CDQ groundfish fisheries under paragraph (c) of this section and § 679.26.

(B) Catcher vessels using trawl gear in the CDQ fisheries under subpart C of this part must retain all salmon and herring prohibited species catch and deliver it to a processor with a valid CDQ permit.

(3) *Rebuttable presumption.* Except as provided under paragraph (c) of this section, § 679.26, or for salmon and herring retained by catcher vessels using trawl gear in the CDQ fisheries, there will be a rebuttable presumption that any prohibited species retained on board a fishing vessel regulated under

this part was caught and retained in violation of this section.

* * * * *

(e) * * *

(1) * * *

(v) *Chinook salmon.* The PSC limit of chinook salmon caught while conducting any non-CDQ trawl fishery for groundfish in the BSAI between January 1 and April 15 is 44,400 fish. A chinook salmon prohibited species catch reserve of 3,600 fish is established for the CDQ fisheries under § 679.31.

(vi) *Non-chinook salmon.* The PSC limit of non-chinook salmon caught while conducting any non-CDQ trawl fishery for groundfish in the CVOA between August 15 and October 14 is 38,850 fish. A non-chinook salmon prohibited species catch reserve of 3,150 fish is established for the CDQ fisheries under § 679.31.

(3) * * *

(iv) * * *

(G) *CDQ fisheries.* 7.5 percent of the PSC limits are apportioned to the CDQ fisheries under § 679.31.

(4) * * *

(ii) * * *

(F) *CDQ fisheries.* 7.5 percent of the non trawl halibut PSC limit is apportioned to the CDQ fisheries under § 679.31.

9. In § 679.23, paragraph (e)(3) is amended by revising the headings of paragraphs (e)(3) (i) and (ii) and by adding paragraph (e)(3)(iii) to read as follows:

§ 679.23 Seasons.

* * * * *

(e) * * * * *

(3) * * *

(i) *Halibut CDQ.* * * *

(ii) *Sablefish CDQ.* * * *

(iii) *Groundfish CDQ.* Directed fishing for groundfish species, other than fixed gear sablefish under the Western Alaska CDQ program, pursuant to subpart C of this part is authorized from 0001 hours, A.l.t., January 1, through the end of the fishing year, except as provided in paragraph (c) of this section.

* * * * *

10. In subpart B, § 679.28 proposed to be amended at 62 FR 32564, is further proposed to be amended by revising paragraph (a) and adding new paragraphs (c) through (f) as follows:

§ 679.28 Equipment and Operational Requirements for Catch Weight Measurement.

(a) *Applicability.* This section contains the requirements for scales certified by NMFS to weigh catch at sea, scales certified by the State of Alaska, observer sampling stations, and certified bins for volumetric estimates of catch

weight. Requirements for specific vessels or processors to use this equipment are made elsewhere in this part.

* * * * *

(c) *Scales certified by the State of Alaska.* Scales used to weigh groundfish catch that also are required to be certified by the State of Alaska under Alaska Statutes 45.75 must meet the following requirements.

(1) *Certification.* The scale must display a valid State of Alaska certification sticker indicating that the scale was certified within 12 months of the date of inspection.

(2) The scale and scale display must be visible simultaneously to the observer. Observers, NMFS personnel, or an authorized officer must be allowed to observe the weighing of fish on the scale and be able to read the scale display at all times.

(3) *Printed scale weights.* Printouts of the scale weight of each haul, set, or delivery must be made available to observers, NMFS personnel, or an authorized officer at the time they are printed and anytime thereafter for the duration of the fishing year. Printouts must be retained by the operator or manager as specified in § 679.5(a)(15).

(d) *Observer Sampling Station—(1) Accessibility.* All of the equipment required for an observer sampling station must be [made] available to the observer at all times while a sampling station is required and the observer is on board the vessel.

(2) *Location—(i) Motherships or catcher/processors and catcher vessels using trawl gear.* The observer sampling station must be located within 4 m of the location from which the observer samples unsorted catch.

(ii) *Longline or pot catcher vessels or catcher/processors.* The observer sampling station must be located within 3 m of the location where fish are brought on board the vessel.

(3) *Minimum work space.* The observer must have a working area at least 1.8 m wide by 2.5 m long including the observer's sampling table, for sampling and storage of fish to be sampled. The observer must be able to stand upright in the area in front of the table and scale.

(4) *Table.* The observer's sampling table must be at least 0.6 m deep, 1.2 m wide and 0.9 m high and must not be more than 1.1 m high. The entire surface area of the table must be available for use by the observer. Any area used for the motion-compensated platform scale is in addition to the minimum space requirements for the table. The observer's sampling table must be secured to the floor or wall.

(5) *Motion-compensated platform scale*—(i) *Specifications*. The electronic motion-compensated platform scale must have a capacity of at least 50 kg. The scale must be mounted within 1 m of the observer's sampling table.

(ii) *Test weights*. At least two 5-kg, two 10-kg, and one 20-kg test weights must be on board the vessel at all times when an observer sampling station is required. Each test weight must have an identifying number or character code stamped or otherwise permanently affixed to it. The identification number and weight of each test standard to the nearest 0.1 kg must be verified in writing annually by the scale manufacturer or a scale inspector authorized by the Regional Administrator. This written verification must be signed and dated and be on board the vessel at all times.

(iii) *Maximum permissible error at sea*. The motion-compensated platform scale must weigh the test weights to within the maximum permissible error specified in Appendix A, section 4, Table 1 when tested at sea by an observer.

(6) *Other requirements*. The sampling station must include floor grating, adequate lighting, and a hose that supplies fresh or sea water to the observer.

(7) *Requirements for sampling catch*. On motherships and catcher/processors using trawl gear, the conveyor belt conveying unsorted catch must have a removable board to allow fish to be diverted from the belt directly into the observer's sampling baskets. The diverter board must be located after the certified scale used to weigh total catch so that the observer can use this scale to weigh large samples.

(e) *Certified bins for volumetric estimates of catch weight*—(1) *Certification*. The information required in this paragraph must be prepared, dated, and signed by a licensed engineer with no financial interest in fishing, fish processing, or fish tender vessels. Complete bin certification documents must be submitted to the Regional Administrator prior to harvesting or receiving groundfish from a fishery in which certified bins are required and must be on board the vessel and must be available to the observer at all times.

(2) *Specifications*—(i) *Measurement and marking*. The volume of each bin must be determined by accurate measurement of the internal dimensions of the bin. The internal walls of the bin must be permanently marked and numbered in 10-cm increments indicating the level of fish in the bin in cm. All marked increments and numerals must be readable from the

outside of the bin through a viewing port or hatch at all times. Marked increments are not required on the wall in which the viewing port is located unless such increments are necessary to determine the level of fish in the bin from another viewing port. Bins must be lighted in a manner that allows marked increments to be read from the outside of the bin by an observer or authorized officer. For bin certification documents dated after [insert date 30 days after date of publication of the final rule in the **Federal Register**], the numerals at the 10-cm increment marks must be at least 4 cm high.

(ii) *Viewing ports*. Each bin must have a viewing port or ports from which the internal bin markings and numerals on all walls of the bin, except the wall in which the viewing port is placed, can be seen from the outside of the bin.

(3) *Information required*. For bin certification documents submitted after [insert date 30 days after date of publication of the final rule in the **Federal Register**], the person certifying the bins must provide:

(i) The vessel name.

(ii) The date the engineer measured the bins and witnessed the location of the marked increments and numerals.

(iii) A diagram, to scale, of each bin showing the location of the marked increments on each internal wall of the bin, the location, and dimensions of each viewing port or hatch, and any additional information needed to estimate the volume of fish in the bin.

(iv) Tables indicating the volume of each certified bin in cubic meters for each 10-cm increment marked on the sides of the bins.

(v) Instructions for determining the volume of fish in each bin from the marked increments and table.

(vi) The person's name and signature and date the completed bin certification documents were signed.

(4) *Recertification*. The bin's volume and marked and numbered increments must be recertified if the bin is modified in a way that changes its size or shape or if marking strips or marked increments are moved or added.

(5) *Operational requirements*—(i) *Placement of catch in certified bins*. All catch must be placed in a bin certified under this paragraph to estimate total catch weight prior to sorting. Refrigerated seawater tanks may be used for volumetric estimates only if the tanks comply with all other requirements of this paragraph, no water is in the tanks before fish are added, and no water is added to the tanks before the observer records the level of fish in the tank. No adjustments of volume will be

made for the presence of water in the bin or tank.

(ii) *Prior notification*. Vessel operators must notify observers prior to any removal or addition of fish from each bin used for volumetric measurements of catch so that an observer may make bin volume estimates prior to fish being removed from or added to the bin. Once a volumetric estimate has been made, additional fish may not be added to the bin until at least half the original volume has been removed. Fish may not be removed from or added to a bin used for volumetric estimates of catch weight until an observer indicates that bin volume estimates have been completed and any samples of catch required by the observer have been taken.

(iii) Fish from separate hauls or deliveries from separate harvesting vessels may not be mixed in any bin used for volumetric measurements of catch.

(iv) The bins must not be filled in a manner that obstructs the viewing ports or prevents the observer from seeing the level of fish throughout the bin.

11. Section 679.30 is revised to read as follows:

§ 679.30 General CDQ regulations.

(a) *Application procedure*. The CDQ program is a voluntary program. Allocations of CDQ and PSQ are made to CDQ groups and not to vessels or processors fishing under contract with any CDQ group. Any vessel harvesting or processing CDQ or PSQ under a CDP must comply with all other requirements of this part. Allocations of CDQ and PSQ are harvest privileges that expire upon the expiration of the CDP. When a CDP expires, further CDQ allocations are not implied or guaranteed, and a CDQ group must re-apply for further allocations on a competitive basis with other CDQ groups. The CDQ allocations provide the means for CDQ groups to complete their CDQ projects. A CDQ group may apply for CDQ and PSQ allocations by submitting a proposed CDP to the State during the CDQ application period which will be announced by the State. A proposed CDP must be submitted by a qualified applicant and must include:

(1) *Community development information*. Community development information includes:

(i) *Project description*. A detailed description of all proposed CDQ projects, including the short- and long-term benefits to the CDQ group from the proposed CDQ projects. CDQ projects should not be designed with the expectation of CDQ allocations beyond those requested in the proposed CDP.

(ii) *Project schedule.* A schedule for the completion of each CDQ project with measurable milestones for determining the progress of each CDQ project.

(iii) *Employment.* The number of individuals to be employed through the CDP projects, and a description of the nature of the work and the career advancement potential for each type of work.

(iv) *Community eligibility.* A list of the participating communities. Each participating community must be listed in Table 7 of this part or meet the criteria for an eligible community under § 679.2.

(v) *Community support.* A demonstration of each participating community's support for the CDQ group and the managing organization participating through an official letter approved by the governing body of each such community.

(2) *Managing organization information.* A proposed CDP must include the following information about the managing organization:

(i) *Structure and personnel.* A description of the management structure and key personnel, such as resumes and references, including the name, address, fax number, and telephone number of the CDQ representative.

(ii) *Management qualifications.* A description of how the managing organization is qualified to carry out the CDP projects in the proposed CDP, and a demonstration that the managing organization has the management, technical expertise, and ability to manage CDQ allocations and prevent exceeding a CDQ or PSQ.

(iii) *Legal relationship.* Documentation of the legal relationship between the CDQ group and the managing organization (if the managing organization is different from the CDQ group) clearly describing the responsibilities and obligations of each party as demonstrated through a contract or other legally binding agreement.

(iv) *Board of directors.* The name, address, and telephone number of each member of the board of directors of the CDQ group. If a qualified applicant represents more than one community, the board of directors of the qualified applicant must include at least one member elected in an at-large election by his or her community, for each community in the CDQ group. For the purposes of this paragraph, election-at-large means that all registered voters in the community are eligible to vote.

(3) *Business information.* A proposed CDP must include the following business information:

(i) *Business relationships.* A description of all business relationships between the CDQ group and all individuals who have a financial interest in a CDQ project or subsidiary venture, including but not limited to, any arrangements for management and audit control and any joint venture arrangements, loans, or other partnership arrangements, including the distribution of proceeds among the parties.

(ii) *Profit sharing.* A description of all profit sharing arrangements.

(iii) *Funding.* A description of all funding and financing plans.

(iv) *General budget for implementing the CDP.* A general account of estimated income and expenditures for each CDQ project for the total number of calendar years that the CDP is in effect.

(v) *Financial statement for the CDQ group.* The most recent audited income statement, balance sheet, cash flow statement, management letter, and agreed upon procedures report.

(vi) *Organizational chart.* A visual representation of the CDQ group's entire organizational structure including all divisions, subsidiaries, joint ventures, and partnerships. This chart must include the type of legal entity, state of registration, and percentage of ownership.

(4) *Request for CDQ and PSQ allocations.* A list of the percentage of each CDQ reserve and PSQ reserve, as defined at § 679.31 (b)–(g), that is being requested. The request for allocations of CDQ and PSQ must identify percentage allocations requested for target species and bycatch species for each target fishery. Target fishery designations must include the primary target species of the fishery and gear type of the vessel that will be used to harvest the catch.

(5) *Fishing plan for groundfish and halibut CDQ fisheries.* The following information must be provided for all vessels and processors that will be harvesting groundfish and halibut CDQ.

(i) *List of eligible vessels and processors—(A) Vessels.* A list of the name, Federal fisheries permit number (if applicable), ADF&G vessel number, LOA, gear type, and vessel type (catcher vessel, catcher/processor, or mothership) for each vessel that will be used to catch or process CDQ and PSQ. Any CDQ vessel that is exempt from the License Limitation Program under § 679.4(i)(2)(iv) must be identified as such.

(B) *Shoreside processors or buying stations.* A list of the name, Federal processor permit number, and location of each shoreside processor or buying station that is required to have a Federal processor permit under § 679.4(f) and

will take deliveries of, or process, CDQ catch.

(C) *Buyers of halibut CDQ.* A list of processors of halibut CDQ that are not required to have a Federal Processor Permit under § 679.4(f), including the name of the buyer or processor, mailing address, telephone number, and location where halibut CDQ will be landed.

(ii) *Sources of data or methods for estimating CDQ and PSQ catch.* The sources of data or methods that will be used to estimate catch weight of CDQ and PSQ for each vessel or processor proposed as eligible under the CDP. For each vessel or processor, the CDP must specify whether the NMFS' standard sources of data set forth at § 679.32(e)(3) or some other alternative will be used. For catcher vessels using nontrawl gear, the CDP also must specify whether the vessel will be retaining all groundfish CDQ or will be discarding some CDQ catch at sea. The CDQ group may propose the use of an alternative method such as the sorting and weighing all catch by species on processor vessels or using larger sample sizes than would be required under § 679.32(e)(3). Alternatives to the requirement for a certified scale or an observer sampling station may not be proposed. NMFS will review the proposal for the requirements specified in paragraphs (a)(5)(ii) (A) through (D) of this section:

(A) The alternative proposed will provide equivalent or better estimates than use of the NMFS standard data source.

(B) Each haul, set, or pot on an observed vessel can be sampled by an observer for species composition.

(C) Any proposal to sort catch before it is weighed assures that the sorting and weighing process will be monitored by an observer.

(D) The CDQ observer is required to be on duty no more than 12 hours in each 24-hour period and is required to sample no more than 9 hours in each 24-hour period.

(E) The CDQ observer on a vessel using trawl gear is required to sample no more than 3 hauls in each 24-hour period. NMFS will review the proposal and approve it or notify the CDQ group in writing if the proposed alternative does not meet these requirements. The CDQ group may remove the vessel or processor for which the alternative method is proposed from the proposed CDP to facilitate approval of the CDP and add the vessel or processor to the CDP by amendment at a later date.

(iii) *Amendments to the list of eligible vessels and processors.* The list of eligible vessels and processors may be

amended by submitting the information required in paragraphs (a)(5) (i) and (ii) of this section as a technical amendment to the CDP.

(6) *CDQ planning*—(i) *Transition plan*. A proposed CDP must include an overall plan and schedule for transition from reliance on CDQ allocations to self-sufficiency in fisheries for each CDQ project.

(ii) *Post-allocation plan*. [Reserved]

(b) *Public hearings on CDQ application*. When the CDQ application period has ended, the State must hold a public hearing to obtain comment on the proposed CDPs from all interested persons. The hearing must cover the substance and content of proposed CDPs so that the general public, and particularly the affected parties, have a reasonable opportunity to understand the impact of the proposed CDPs. The State must provide reasonable public notification of hearing date and location. The State must make available for public review, at the time of public notification of the hearing, all State materials pertinent to the hearing.

(c) *Council consultation*. Before the State sends its recommendations for approval of proposed CDPs to NMFS, the State must consult with the Council, and make available, upon request, proposed CDPs that are not part of the State's recommendations.

(d) *Review and approval of proposed CDPs*. The State must transmit the proposed CDPs and its recommendations for approval of each of the proposed CDPs to NMFS along with the findings and the rationale for the recommendations by October 7. The State shall determine in its recommendations for approval of the proposed CDPs that each proposed CDP meets all applicable requirements of this part. Upon receipt by NMFS of the proposed CDPs and the State's recommendations for approval, NMFS will review the proposed CDPs and approve those that it determines meet all applicable requirements. In the event of approval of the CDP, NMFS will notify the State in writing that the proposed CDP is approved by NMFS and is consistent with all requirements for CDPs. If NMFS finds that a proposed CDP does not comply with the requirements of this part, NMFS must so advise the State in writing, including the reasons therefor. The State may submit a revised proposed CDP along with revised recommendations for approval to NMFS.

(e) *Transfer*. CDQ groups may request NMFS to transfer CDQ allocations, CDQ, PSQ allocations, or PSQ from one to another by each group filing an appropriate amendment to its CDP. If

NMFS approves both amendments, NMFS will make the requested transfer(s) by decreasing the account balance of the CDQ group from which the CDQ or PSQ species is transferred by the amount transferred, and by increasing the account balance of the CDQ group receiving the transferred CDQ or PSQ species by the amount transferred.

(1) *CDQ allocation*. CDQ groups may request that NMFS transfer any or all of one group's CDQ allocation to another by each group filing an amendment to its CDP through the CDP substantial amendment process set forth at paragraph (g)(4) of this section. The CDQ allocation will be transferred as of January 1 of the calendar year following the calendar year NMFS approves the amendments of both groups and is effective for the duration of the CDPs.

(2) *CDQ*. CDQ groups may request that NMFS transfer any or all of one group's CDQ for a calendar year to another by each group filing an appropriate amendment to its CDP. If the amount to be transferred is 10 percent or less of a group's CDQ, that group's request may be made through the CDP technical amendment process set forth at paragraph (g)(5) of this section. If the amount to be transferred is greater than 10 percent of a group's CDQ, that group's request must be made through the CDP substantial amendment process set forth at paragraph (g)(4) of this section. The CDQ will be transferred as of the date NMFS approves the amendments of both groups and is effective only for the remainder of the calendar year in which the transfer occurs.

(3) *PSQ allocation*. CDQ groups may request that NMFS transfer any or all of one group's PSQ allocation to another CDQ group through the CDP substantial amendment process set forth at paragraph (g)(4) of this section. Each group's request must be part of a request for the transfer of a CDQ allocation and the requested amount of PSQ allocation must be the amount reasonably required for bycatch needs during the harvesting of the CDQ. Requests for the transfer of a PSQ allocation may be submitted to NMFS only from January 1 through January 31. The PSQ allocation will be transferred as of January 1 of the calendar year following the calendar year NMFS approves the amendments of both groups and is effective for the duration of the CDPs.

(4) *PSQ*. CDQ groups may request that NMFS transfer any or all of one group's PSQ for a calendar year to another by each group filing an amendment to its CDP through the CDP substantial amendment process set forth at

paragraph (g)(4) of this section. Each group's request must be part of a request for the transfer of a PSQ and the requested amount of PSQ must be the amount reasonably required for bycatch needs during the harvesting of the CDQ. Requests for the transfer of PSQ may be submitted to NMFS only from January 1 through January 31. The PSQ will be transferred as of the date NMFS approves the amendments of both groups and is effective only for the remainder of the calendar year in which the transfer occurs.

(f) *CDQ group responsibilities*. A CDQ group must:

(1) Direct and supervise all activities of the managing organization.

(2) Maintain the capability to communicate with all vessels harvesting its CDQ and PSQ at all times.

(3) Monitor the catch of each CDQ or PSQ.

(4) Submit the CDQ check-in/check-out report and CDQ catch report described at § 679.5 (m) and (n).

(5) Ensure that no CDQ or halibut PSQ is exceeded.

(6) Ensure that the CDQ group's CDQ harvesting vessels and CDQ processors will:

(i) Provide observer coverage, equipment, and operational requirements for CDQ catch monitoring.

(ii) Provide for the communication of observer data from their vessel to NMFS and the CDQ representative.

(iii) Maintain contact with the CDQ group for which it is harvesting CDQ and PSQ.

(iv) Cease fishing operations when requested by the CDQ group.

(7) Comply with all requirements of this part.

(g) *Monitoring of CDPs*—(1) *Annual progress report*—(i) The State must submit to NMFS, by October 30 of each year, an annual progress report for the previous calendar year for each CDP.

(ii) Annual progress reports must be organized on a project-by-project basis and include information for each CDQ project in the CDP describing how each scheduled milestone in the CDP has been met, and an estimation by the State of whether each of the CDQ projects in the CDP is likely to be successful.

(iii) The annual report must include a description by the State of any problems or issues in the CDP that the State encountered during the annual report year.

(2) *Annual budget report*. (i) Each CDQ group must submit to NMFS an annual budget report by December 15 preceding the year for which the annual budget applies.

(ii) An annual budget report is a detailed estimate of the income from the

CDQ project and of the expenditures for each subsidiary, division, joint venture, partnership, investment activity, or CDQ project as described in paragraph (a)(1)(i) of this section for a calendar year. A CDQ group must identify the administrative costs for each CDQ project. The CDQ group's total administrative costs will be considered a separate CDQ project.

(iii) An annual budget report is approved upon receipt by NMFS, unless disapproved by NMFS in writing by December 31. If disapproved, the annual budget report will be returned to the CDQ group for revision and resubmittal to NMFS.

(3) *Annual budget reconciliation report.* A CDQ group must reconcile its annual budget by May 30 of the year following the year for which the annual budget applied. Reconciliation is an accounting of the annual budget's estimated income and expenditures with the actual income and expenditures, including the variance in dollars and variance in percentage for each CDQ project that is described in paragraph (a)(1)(i) of this section. If a general budget, as submitted in accordance with paragraph (a)(3)(iv) of this section, is no longer accurate due to the reconciliation of an annual budget, then the general budget must also be revised to reflect the annual budget reconciliation. The revised general budget must be included with the annual budget reconciliation report.

(4) *Substantial amendments.* A CDP is a working business plan and must be kept up to date.

(i) Substantial amendments to a CDP require written notification by the CDQ group to the State. The State must forward the amendment to NMFS with a recommendation as to whether it should be approved.

(ii) NMFS will notify the State in writing of the approval or disapproval of the amendment within 30 days of receipt of the amendment and the State's recommendation. Except for substantial amendments for the transfer of CDQ and PSQ which are effective only for the remainder of the calendar year in which the transfer occurs (see paragraphs (e) (2) and (4) of this section), once a substantial amendment is approved by NMFS, the amendment will be effective for the duration of the CDP.

(iii) If NMFS determines that the CDP, if changed, would no longer meet the requirements of this subpart, NMFS will notify the State in writing of the reasons why the amendment cannot be approved.

(iv) For the purposes of this section, substantial amendments are defined as

changes in a CDP, including, but not limited to:

(A) Any change in the applicant communities or replacement of the managing organization.

(B) A change in the CDP applicant's harvesting or processing partner.

(C) Funding a CDP project in excess of \$100,000 that is not part of an approved general budget.

(D) More than a 20-percent increase in the annual budget of an approved CDP project.

(E) More than a 20-percent increase in actual expenditures over the approved annual budget for administrative operations.

(F) A change in the contractual agreement(s) between the CDP applicant and its harvesting or processing partner, or a change in a CDP project, if such change is deemed by the Governor or NMFS to be a material change.

(G) Any transfer of a CDQ allocation, PSQ allocation, PSQ, or a transfer of more than ten percent of a CDQ.

(v) Notification of an amendment to a CDP shall include the following information:

(A) The background and justification for the amendment that explains why the proposed amendment is necessary and appropriate.

(B) An explanation of why the proposed change to the CDP is a substantial amendment.

(C) A description of the proposed amendment, explaining all changes to the CDP that result from the proposed amendment.

(D) A comparison of the original CDP text with the text of the proposed changes to the CDP, and the revised pages of the CDP for replacement in the CDP binder. The revised pages must have the revision date noted with the page number on all affected pages. The table of contents may also need to be revised to reflect any changes in pagination.

(E) Identification of any NMFS findings that would need to be modified if the amendment is approved along with the proposed modified text.

(F) A description of how the proposed amendment meets the requirements of this subpart. Only those CDQ regulations that are affected by the proposed amendment need to be discussed.

(5) *Technical amendments.* Any change to a CDP that is not a substantial amendment as defined in paragraph (g)(4)(iv) of this section is a technical amendment.

(i) The CDQ group must notify the State in writing of any technical amendment. Such notification must include a copy of the pages of the CDP

that would be revised by the amendment, with the text highlighted to show the proposed deletions and additions, and a copy of the CDP pages as they would be revised by the proposed amendment for insertion into the CDP binder. All revised CDP pages must include the revision date, amendment identification number, and CDP page number. The table of contents may also need to be revised to reflect any changes in pagination.

(ii) The State must forward the technical amendment to NMFS with its recommendations for approval or disapproval of the amendment. A technical amendment is approved by NMFS and is effective when NMFS notifies the State in writing of the technical amendment's receipt.

12. Section 679.31 is revised to read as follows:

§ 679.31 CDQ reserves.

(a) *Non-specific CDQ reserve.* Annually, NMFS will apportion 15 percent of each squid, arrowtooth flounder, and "other species" CDQ for each CDQ group to a non-specific CDQ reserve. A CDQ group's non-specific CDQ reserve must be for the exclusive use of that CDQ group. A release from the non-specific CDQ reserve to its squid, arrowtooth flounder, or "other species" is a technical amendment as described in § 679.30(g)(5). The technical amendment must be approved before harvests relying on CDQ transferred from the non-specific CDQ reserve may be conducted.

(b) *Pollock CDQ reserve* (applicable through December 31, 1998). In the proposed and final harvest specifications required under § 679.20(c), one-half of the pollock TAC placed in the reserve for each subarea or district of the BSAI will be apportioned to a CDQ reserve for each subarea or district.

(c) *Halibut CDQ reserve.* (1) NMFS will annually withhold the proportions of the halibut catch limit that are specified in paragraph (c)(2) of this section for use as a CDQ reserve.

(2) The proportions of the halibut catch limit annually withheld for purposes of the CDQ program, exclusive of issued QS, are as follows for each IPHC regulatory area:

(i) Area 4B. In IPHC regulatory area 4B, 20 percent of the annual halibut quota shall be made available for the halibut CDQ program to eligible communities physically located in or proximate to this regulatory area. For the purposes of this section, "proximate to" an IPHC regulatory area means within 10 nm from the point where the

boundary of the IPHC regulatory area intersects land.

(ii) Area 4C. In IPHC regulatory area 4C, 50 percent of the halibut quota shall be made available for the halibut CDQ program to eligible communities physically located in IPHC regulatory area 4C.

(iii) Area 4D. In IPHC regulatory area 4D, 30 percent of the halibut quota shall be made available for the halibut CDQ program to eligible communities located in or proximate to IPHC regulatory areas 4D and 4E.

(iv) Area 4E. In IPHC regulatory area 4E, 100 percent of the halibut quota shall be made available for the halibut CDQ program to communities located in or proximate to IPHC regulatory area 4E. A fishing trip limit of 6,000 lb (2.7 mt) will apply to halibut CDQ harvesting in IPHC regulatory area 4E.

(d) *Sablefish CDQ reserves*—(1) *Fixed gear sablefish CDQ reserve*. In the proposed and final harvest limit specifications required under § 679.20(c), NMFS will specify 20 percent of the fixed gear allocation of sablefish in each subarea or district of the BSAI as a fixed-gear sablefish CDQ reserve, exclusive of issued QS.

(2) *Sablefish CDQ reserve*. In the proposed and final harvest limit specifications required under § 679.20(c), NMFS will specify 7.5 percent of the trawl gear allocation of sablefish in each subarea or district of the BSAI as a sablefish CDQ reserve.

(e) *Groundfish CDQ reserve*. In the proposed and final harvest specifications required under § 679.20(c), one-half of the amount of each groundfish TAC that is placed in the reserve for each subarea or district of the BSAI will be apportioned to a separate CDQ reserve for each subarea or district. The groundfish CDQ reserve does not include sablefish. If the proposed and final harvest limit specifications required under § 679.20(c) change the groundfish species comprising the “other species” category, then any CDQ allocations of “other species” category groundfish would change according to the changed species mix of the “other species” category.

(f) *Crab CDQ reserve*. The following percentages of the king and Tanner crab in the Bering Sea and Aleutian Islands Area that has a guideline harvest level specified by the State that is available for commercial harvest will be apportioned to a crab CDQ reserve:

(1) For calendar year 2000, and thereafter, 7.5 percent.

(2) For calendar year 1999 (applicable through December 31, 1999), 5 percent.

(3) For calendar year 1998 (applicable through December 31, 1998), 3.5 percent.

(g) *PSQ reserve*. Seven and one-half percent of the PSC limits specified at § 679.21(e) for red king crab in Zone 1, Tanner crab (*C. bairdi*) in Zone 1, Tanner crab in Zone 2, halibut, and Pacific herring will be apportioned to PSQ reserves. 3,600 chinook salmon and 3,150 non-chinook salmon will be apportioned to PSQ reserves.

13. Section 679.32 is revised to read as follows:

§ 679.32 Groundfish and halibut CDQ catch monitoring.

(a) *Applicability*. (1) The CDQ representative, the operator or manager of a buying station, the operator of a vessel, and the manager of a shoreside processor fishing in the groundfish or halibut CDQ fisheries must comply with the requirements of this section.

(2) *Pollock, halibut, and fixed-gear sablefish CDQ fishing in 1998* (applicable through December 31, 1998). Regulations governing the catch of pollock, halibut, fixed-gear sablefish CDQ in 1998 are at paragraphs (f) and (g) of this section. Vessels and processors harvesting only these CDQ species are not required to comply with paragraphs (b) through (e) of this section in 1998, unless specifically required to do so in paragraphs (f) and (g). The catch of pollock with any authorized gear and sablefish with fixed gear in the multispecies CDQ fisheries in 1998 will not accrue to the CDQs for these species.

(b) *Prohibited species catch*. Time and area closures required once the CDQ group has reached its salmon, herring, or crab PSQs are listed in § 679.7(d) (7) through (11). The catch of salmon, crab, or herring PSQ by vessels using other than trawl gear and the catch of halibut PSQ by vessels using pot gear does not accrue to the PSQ for these species.

(c) *Gear restrictions*. Fixed gear sablefish and halibut CDQ must be harvested with fixed gear only. Catch of sablefish with fixed gear may accrue to the fixed gear sablefish CDQ reserve or the sablefish CDQ reserve. Catch of sablefish with other than fixed gear will accrue to the sablefish CDQ reserve.

(d) *Requirements for vessels and processors*. Vessels and processors participating in the CDQ fisheries must comply with the following requirements.

(1) *Catcher vessels without observers*.

(i) Catcher vessels less than 60 ft (18.3 m) LOA must retain all groundfish and halibut CDQ until it is delivered to a processor with a valid CDQ permit.

(ii) Catcher vessels using trawl gear must discard halibut and crab PSQ at-

sea. The weight of halibut PSQ and numbers of crab PSQ must be reported on the ADF&G fish ticket within 24 hours of the completion of the fishing trip.

(iii) Catcher vessels using non-trawl gear must discard all halibut PSQ at sea and report the weight of halibut discarded on the ADF&G fish ticket within 24 hours of the completion of the fishing trip.

(2) *Catcher vessels with observers*. Catcher vessels equal to or greater than 60 ft (18.3 m) LOA must comply with the following requirements in addition to complying with the minimum observer coverage requirements at § 679.50(c)(4).

(i) If using trawl gear must,

(A) Retain all CDQ species, salmon PSQ, and herring PSQ until it is delivered to a processor with a valid CDQ permit.

(B) Retain all halibut and crab PSQ in a bin or other location until it is counted and sampled by a CDQ observer.

(C) Provide space on the deck of the vessel for the CDQ observer to sort and store catch samples and a place from which to hang the observer sampling scale.

(ii) If using non-trawl gear, either

(A) *Retain all CDQ Species*. Retain all CDQ species until they are delivered to a processor with a valid CDQ permit and have all of the halibut PSQ counted by the CDQ observer and sampled for average weight.

(B) *Discard Some CDQ Species At-Sea*. May discard some CDQ species at sea if the following requirements are met.

(1) *Sampling station*. The vessel owner provides an observer sampling station that complies with § 679.28(d) so that the CDQ observer can accurately determine the average weight of discarded CDQ species.

(2) *CDQ permit*. A valid CDQ permit is on board the vessel at all times while harvesting, processing, or transporting CDQ.

(3) *Species composition*. Each set or pot is sampled for species composition by a CDQ observer.

(4) *Catch weight and numbers*. The CDQ group specifies in the CDP that the CDQ and PSQ catch weight and numbers will be based on the CDQ observer's estimates rather than the processor's report of landed catch weight and numbers.

(3) *Shoreside processors and buying stations*. All shoreside processors and buying stations taking CDQ deliveries in addition to complying with the minimum observer coverage requirements at § 679.50(d)(4) must:

(i) *CDQ permit*. Have a valid CDQ permit on site at the shoreside processor at all times.

(ii) *CDQ and PSQ by weight*. Sort and weigh on a scale certified under § 679.28(c), all groundfish and halibut CDQ or PSQ and any halibut and herring PSQ delivered to a shoreside processor or buying station by CDQ or PSQ species or species group.

(iii) *PSQ by number*. The shoreside processor must count all salmon or crab PSQ.

(iv) *Prior notice of offloading schedule*. The manager of each shoreside processor or buying station must notify the CDQ observer(s) of the offloading schedule of each CDQ groundfish delivery at least 1 hour prior to offloading to provide the CDQ observer an opportunity to monitor the weighing of the entire delivery.

(v) *CDQ and PSQ sorting and weighing*. All sorting and weighing of CDQ and PSQ must be monitored by a CDQ observer.

(4) *Catcher/processors and motherships*. Catcher/processors and motherships in addition to complying with the minimum observer coverage requirements described at § 679.50(c)(4) must:

(i) *CDQ permit*. Have a valid CDQ permit on board the vessel at all times harvesting, processing, or transporting CDQ.

(ii) *Observer sampling station*. Provide an observer sampling station as described at § 679.28(d).

(iii) *Catcher/processors using trawl gear and motherships*. Catcher/processors using trawl gear and motherships must weigh all catch on a scale certified under § 679.28(b) of this part. Catch from each haul must be weighed separately. Catch must not be sorted before it is weighed unless a CDQ provision for doing so is approved by NMFS for the vessel. Each CDQ haul must be sampled by a CDQ observer for species composition and the vessel operator must allow CDQ observers to use the certified scale to weigh partial haul samples.

(iv) *Catcher/processors using non-trawl gear*. Each CDQ set or pot must be sampled by a CDQ observer for species composition and average weight.

(e) *Recordkeeping and reporting*—(1) *Check-in/check-out report*. The CDQ representative must submit the CDQ check-in/check-out report and the CDQ catch report described at § 679.5 (m) and (n).

(2) *Catch record*. The operator or manager of a buying station, the operator of a vessel, and the manager of a shoreside processor must record all catch in the CDQ fisheries, including all

groundfish species and prohibited species caught, taken, or harvested in each haul or set as required at § 679.5.

(3) *Verification of CDQ and PSQ catch reports*. CDQ groups may specify the sources of data listed below as the sources they will use to report CDQ catch by specifying “NMFS standard sources of data” in their CDP. In the case of a catcher vessel using non-trawl gear, the CDP must specify whether any CDQ species will be discarded at sea. CDQ species may be discarded at sea only if the requirements of paragraph (d)(2)(ii)(A) of this section are met. NMFS will use the following sources to verify the CDQ catch reports unless an alternative catch estimation procedure in the CDP is approved by NMFS under § 679.30(a)(5)(ii).

(i) *Unobserved catcher vessels*. The weight or numbers of all CDQ and PSQ species on ADF&G fish tickets if all CDQ species, salmon PSQ, and herring PSQ are retained on board the vessel, delivered to a processor with a valid CDQ permit, and sorted and weighed in compliance with paragraph (d)(3) of this section.

(ii) *Observed catcher vessels using trawl gear*. The CDQ observer's estimate of halibut and crab PSQ and the weight or numbers of all groundfish CDQ, salmon PSQ, and herring PSQ on ADF&G fish tickets if all CDQ species, salmon PSQ, and herring PSQ are retained on board the vessel, delivered to a processor with a valid CDQ permit, and sorted and weighed in compliance with paragraph (d)(3) of this section.

(iii) *Observed catcher vessels using non-trawl gear*. (A) The CDQ observer's estimates of the weight of halibut PSQ and the weight or numbers of CDQ species on ADF&G fish tickets if all CDQ species are retained on board the vessel, delivered to a processor with a valid CDQ permit, and sorted and weighed in compliance with paragraph (d)(3) of this section; or

(B) The CDQ observer's estimate of the weight of all CDQ and PSQ species if any CDQ species are discarded at sea.

(iv) *Catcher/processors using trawl gear and motherships*. The CDQ observer's estimate of the weight and numbers of CDQ and PSQ species as determined by applying the CDQ observer's species composition sampling data for each haul to the total weight of haul as determined by weighing all catch from each haul on a scale certified under § 679.28(b).

(v) *Catcher/processors using non-trawl gear*. The CDQ observer's estimates of the weight and numbers of CDQ and PSQ species as determined by sampling each set or pot to determine

the number and average weight of each CDQ and PSQ species.

(f) *Pollock CDQ (applicable through December 31, 1998)*—(1) *Applicability*. Vessels and processors harvesting pollock CDQ in 1998 must comply with the requirements of this paragraph.

(2) *Catch of non-pollock*. The catch of all non-pollock species for which a TAC or PSC limit is specified will accrue against the non-CDQ groundfish fishery TACs and PSC limits. Regulations governing maximum retainable bycatch amounts in the non-CDQ groundfish fisheries must be complied with while harvesting pollock CDQ.

(3) *Recordkeeping and reporting*. (i) The CDQ representative must submit a CDQ catch report that complies with § 679.5(n). Catch from the pollock CDQ fisheries must be identified separately from catch in other CDQ fisheries on the CDQ catch report. Harvest of species other than pollock in the pollock CDQ fisheries must not be reported on the CDQ catch report.

(ii) The CDQ representative must submit a CDQ check-in/check-out report that complies with § 679.5(m) and states that the vessel will be participating in the pollock CDQ fishery.

(iii) The operator or manager of a buying station, the operator of a vessel, and the manager of a shoreside processor must record all catch in the CDQ fisheries, including all groundfish species and prohibited species caught, taken, or harvested in each haul or set as required at § 679.5.

(4) *Observer coverage*. Two observers are required on all catcher/processors and motherships while harvesting, processing, or taking deliveries of pollock CDQ, one observer is required on all catcher vessels harvesting pollock CDQ, and one observer is required in the shoreside processing plant while pollock CDQ is being delivered, sorted, or processed.

(5) *Estimation of the weight of pollock CDQ*—(i) *Shoreside processors and buying stations*. All pollock CDQ delivered to a shoreside processor or buying station must be weighed on a scale certified under § 679.28(c). The manager of each shoreside processor or buying station must notify the observer(s) of the offloading schedule of each CDQ groundfish delivery at least 1 hour prior to offloading to provide the observer an opportunity to monitor the weighing of the entire delivery.

(ii) *Motherships and catcher/processors*. Operators of mothership and catcher/processors must provide the holding bins and comply with the operational requirements at § 679.28(e) in order for volumetric estimates of total catch weight to be made.

(g) *Sablefish and halibut CDQ fisheries (applicable through December 31, 1998)*—(1) *Applicability*. Vessels and processors harvesting fixed gear sablefish or halibut CDQ in 1998 must comply with the requirements of this paragraph.

(2) *Catch of other groundfish*. All groundfish for which a TAC is specified and all prohibited species caught during the sablefish and halibut CDQ fisheries will accrue to the non-CDQ groundfish TACs and PSC limits. Regulations governing maximum retainable bycatch amounts in the non-CDQ groundfish fisheries must be complied with while harvesting fixed-gear sablefish and halibut CDQ.

(3) *Permits*. The managing organization responsible for carrying out an approved CDQ project must have a halibut and/or sablefish permit issued by the Regional Administrator. A copy of the halibut and/or sablefish CDQ permit must be carried on any fishing vessel operated by, or for, the managing organization and be made available for inspection by an authorized officer. Such halibut and/or sablefish CDQ permit is non-transferable and is effective for the duration of the CDQ project or until revoked, suspended, or modified.

(4) *CDQ cards*. All individuals named on an approved CDP application must have a halibut and/or sablefish CDQ card issued by the Regional Administrator before landing any halibut and/or sablefish. Each halibut and/or sablefish CDQ card will identify a CDQ permit number and the individual authorized by the managing organization to land halibut and/or sablefish for debit against its CDQ allocation.

(5) *Alteration*. No person may alter, erase, or mutilate a halibut and/or sablefish CDQ permit, card, registered buyer permit, or any valid and current permit or document issued under this part. Any such permit, card, or document that has been intentionally altered, erased, or mutilated is invalid.

(6) *Landings*. Halibut and/or sablefish harvested pursuant to a approved CDQ project may be landed only by a person with a valid halibut and/or sablefish CDQ card, and delivered only to a person with a valid registered buyer permit, and reported in compliance with § 679.5(l)(1) and (l)(2).

(7) *Recordkeeping and reporting*. Vessels and processors with Federal fisheries or processor permits under § 679.4(f) must report all catch of groundfish, including sablefish CDQ,

and prohibited species from the fixed gear sablefish and halibut CDQ fisheries on logbooks and weekly production reports required under § 679.5. Catch from the fixed gear sablefish and halibut CDQ fisheries must not be reported on the CDQ catch report in 1998.

14. Sections 679.33 and 679.34 are removed.

15. In § 679.40, existing paragraph (f) is removed and existing paragraph (g) is redesignated as a new paragraph (f).

16. In § 679.43, a new paragraph (p) is added to read as follows:

§ 679.43 Determinations and appeals.

* * * * *

(p) *Issuance of a non-transferable permit*. A non-transferable permit will be issued to a person upon acceptance of his or her appeal of an initial administrative determination denying an application for a license for license limitation groundfish or crab species under § 679.4(i). This non-transferable permit authorizes a person to conduct directed fishing for groundfish or directed fishing for crab species and will have specific endorsements and designations based on the person's claims in his or her application for a license. This non-transferable permit expires upon the resolution of the appeal.

17. In § 679.50, the last sentence of paragraph (a) is revised and new paragraphs (c)(4), (d)(4), and (h)(1)(i) (D) and (E) are added as follows:

§ 679.50 Groundfish Observer Program applicable through December 31, 1997.

(a) * * * Observer coverage for the CDQ fisheries obtained in compliance with paragraphs (c)(4) and (d)(4) of this section may not be used to comply with observer coverage requirements for non-CDQ groundfish fisheries specified in paragraphs (c)(1)(v) and (c)(1)(vii) of this section.

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(c) *Observer requirements for vessels*.
* * *

(4) *Groundfish and halibut CDQ fisheries*. Vessels harvesting groundfish or halibut CDQ must comply with the following minimum observer coverage requirements each day that the vessel harvests, transports, processes, delivers, or takes deliveries of groundfish or halibut CDQ or PSQ. No CDQ observer may be required to be on duty more than 12 hours in a 24-hour period, to sample more than 9 hours in a 24-hour period, or to sample more than 3 hauls in a 24-hour period on a vessel using

trawl gear or a processor taking deliveries from vessels using trawl gear.

(i) *Mothership or catcher/processor*. A mothership or catcher/processor of any length must have at least two CDQ observers as described at paragraph (h)(1)(i) (D) and (E) of this section aboard the vessel, at least one of whom must be certified as a lead CDQ observer.

(ii) *Catcher vessel*. A catcher vessel equal to or greater than 60 ft (18.3 m) LOA, except a catcher vessel that delivers only unsorted codends to a processor or another vessel, must have at least one lead CDQ observer as described at paragraph (h)(1)(i)(E) of this section aboard the vessel.

(d) * * *

(4) *Groundfish and halibut CDQ fisheries*. Each shoreside processor required to have a federal processor permit under § 679.4(f) and taking deliveries of groundfish or halibut CDQ must have at least one lead CDQ observer as described at paragraph (h)(1)(i)(E) of this section present at all times while CDQ is being received or processed.

* * * * *

(h) * * *

(1) * * *

(i) * * *

(D) For purposes of the groundfish and halibut CDQ fisheries a NMFS-certified CDQ observer must meet the following requirements.

(1) Be a prior observer who has completed at least 60 days of observer data collection on a vessel using the same gear type as the CDQ vessel that they will be deployed on.

(2) Receive the rating of 1 for "exceptional" or 2 for "meets expectations" by NMFS for their most recent deployment.

(3) Successfully complete a NMFS-approved CDQ observer training and/or briefing as prescribed by NMFS and available from the Observer Program Office.

(4) Comply with all of the other requirements of this section.

(E) To be certified as a "lead observer" in the groundfish and halibut CDQ fisheries, a NMFS-certified observer must complete at least 20 days of observer data collection on a vessel participating in a CDQ fishery in addition to meeting the requirements of paragraph (h)(1)(i)(D) of this section.

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[FR Doc. 97-21169 Filed 8-14-97; 8:45 am]

BILLING CODE 3510-22-P

Final Rule

Friday
August 15, 1997

Part V

**Department of
Health and Human
Services**

Food and Drug Administration

**21 CFR Parts 201, 312, 314, and 601
Pediatric Patients; Regulations Requiring
Manufacturers To Assess the Safety and
Effectiveness of New Drugs and
Biological Products; Proposed Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Parts 201, 312, 314, and 601**

[Docket No. 97N-0165]

RIN 0910-AB20

Regulations Requiring Manufacturers To Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing new regulations requiring pediatric studies of certain new drug and biological products. Many new drugs and biological products represent treatments that are, at least at times, the best available treatment for children, but most of them have not been adequately tested in the pediatric subpopulation. As a result, product labeling frequently fails to provide directions for safe and effective use in pediatric patients. The proposed rule would attempt to partially address this lack of pediatric use information by requiring that manufacturers of a limited class of new drugs and new biological products provide sufficient data and information to support directions for pediatric use for the claimed indications, before or soon after approval. Manufacturers of a limited class of marketed drugs and biologics would also in compelling circumstances have to provide such data. This proposed rule is part of a comprehensive effort to increase the number of new drugs and biological products with clinically significant use in children that carry adequate labeling for use in that subpopulation.

DATES: Written comments and recommendations by November 13, 1997. Written comments on the information collection provisions should be submitted by September 15, 1997. For further information of the agency's implementation plan, see section VII of **SUPPLEMENTARY INFORMATION** in this document.

ADDRESSES: Submit written comments and recommendations to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Submit written comments on the information collection provision 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: Paula Botstein, Center for Drug Evaluation and Research (HFD-103), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3144, and Ann M. Witt, Office of Policy (HF-22), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5321.

SUPPLEMENTARY INFORMATION:**I. Introduction**

Children are subject to many of the same diseases as adults, and are, by necessity, often treated with the same drugs and biological products as adults. According to the American Academy of Pediatrics, however, only a small fraction of all drugs and biological products marketed in the United States have had clinical trials performed in pediatric patients and a majority of marketed drugs are not labeled for use in pediatric patients or for use in specific pediatric age groups (Ref. 1). A recent FDA survey similarly concluded that most products that are indicated for diseases occurring in both adults and children have very little information about pediatric use in their labeling (Ref. 2). For some products, including vaccines and antibiotics, pediatric use information is generally adequate. Many drugs used in the treatment of both common childhood illnesses and more serious conditions, however, carry little information about use in pediatric patients. Less than half the drugs approved for treatment of human immunodeficiency virus (HIV) infection or accompanying opportunistic infections carry any pediatric safety or effectiveness information, and, of those that do, the data are often incomplete and limited to certain pediatric age groups. Pediatric labeling is also inadequate for such drug classes as steroids, drugs to treat gastrointestinal problems, prescription pain medications, antihypertensives, antidepressants, antirheumatic drugs, and drugs to treat ulcerative colitis.

Safety and effectiveness information for some pediatric age groups is particularly sparse. For example, there is almost no information on use in patients under 2 years of age for most drug classes (Ref. 2).

Many of the drugs and biological products most widely used in pediatric patients carry disclaimers stating that safety and effectiveness in pediatric patients have not been established (Refs. 2 and 3). Based on 1994 data from IMS America, Ltd., a research firm that

provides data on prescription drug usage, FDA compiled a list of the 10 drugs that were most widely prescribed for pediatric patients, on an outpatient basis, despite inadequate pediatric labeling. In each case, the label lacked any use information for the age group prescribed to, or the information was inadequate. The drugs were: Albuterol inhalation solution for nebulization for treatment of asthma (prescribed 1,626,000 times to pediatric patients under 12); Phenergan for treatment of allergic reactions (prescribed 663,000 times to pediatric patients under 2); ampicillin injections for treatment of infection (prescribed 639,000 times to pediatric patients under 12); Auralgan otic solution for treatment of ear pain (prescribed 600,000 times to pediatric patients under 16); Lotrisone cream for treatment of topical infections (prescribed 325,000 times to pediatric patients under 12); Prozac for treatment of depression and obsessive compulsive disorder (prescribed 349,000 times to pediatric patients under 16, including 3,000 times to infants under 1); Intal for treatment of asthma (solution prescribed 109,000 times to pediatric patients under 2; aerosol prescribed 399,000 times to pediatric patients under 5); Zoloft for treatment of depression (prescribed 248,000 times to pediatric patients under 16); Ritalin for treatment of attention deficit disorders and narcolepsy (prescribed 226,000 times to pediatric patients under 6); Alupent for treatment of asthma (184,000 times to pediatric patients under 6). These 10 drugs were thus prescribed over 5 million times in 1 year for pediatric patients in age groups for which the label carried a disclaimer or lacked adequate use information (Ref. 2).

The absence of pediatric labeling information may sometimes require the physician caring for children to choose between prescribing drugs without well-founded dosing and safety information or utilizing other, potentially less effective, therapy.

Inadequate pediatric labeling thus exposes children to the risk of unexpected adverse reactions or lack of optimal treatment. Even after a drug has been used in pediatric patients for some time, and there has been substantial clinical experience with the drug, directions for safe and effective use in pediatric patients are not provided on the label.

Children were once viewed as a population entirely distinct from adults, in whom safety and effectiveness of new drugs had to be established entirely independently. It has become increasingly clear, however, that children may be considered a

demographic subpopulation with many similarities to the adult population. In most cases, drugs and biological products behave similarly in demographic subgroups, including age and gender subgroups, even though there may be variations because of differences in, for example, pharmacokinetics. As FDA has already stated in a **Federal Register** document, where the disease and the drug's effects are similar in adults and children, adequate and well-controlled trials may not be needed in children to establish pediatric use information (59 FR 64240, December 13, 1994) (hereinafter referred to as the 1994 rule).

Although use of a drug in children is no longer considered a new indication (with the exception of specific "pediatric indications"), the development of additional information in pediatric patients is needed to provide appropriate dosing recommendations. Correct pediatric dosing cannot necessarily be extrapolated from adult dosing information using an equivalence based either on weight milligrams per kilogram (mg/kg) or body surface area (mg/square meter (m²)). Potentially significant differences in pharmacokinetics may alter a drug's effect in pediatric patients. The effects of growth and maturation of various organs, maturation of the immune system, alterations in metabolism throughout infancy and childhood, changes in body proportions, and other developmental changes may result in significant differences in the doses needed by pediatric patients and adults. For example, studies have shown that fentanyl, a potent opioid, widely used in anesthetic management of infants and small children but not labeled for use in pediatric patients under 2 years of age, demonstrates differences in clearance between the neonatal period and 2 or more months of age due to improving hepatic blood flow and hepatic microsomal maturation (Ref. 4). Comparable doses in adults and neonates (calculated on a microgram (µg)/kg basis) produce twofold to threefold higher plasma concentrations in neonates (Ref. 5). Pharmacokinetic differences of this kind demonstrate the importance of studying the pharmacokinetics of a drug in pediatric patients of different ages before they are widely exposed to it. Inadequate dosing information may expose pediatric patients to dangerously high doses or to ineffective treatment. The absence of pediatric testing may thus result in less than optimal treatment for many pediatric patients.

Pediatric patients receiving inadequately tested and labeled drugs are also exposed to the risk of unexpected adverse reactions. One of the earliest cases in which serious adverse events were observed in neonates following administration of a drug that had not been adequately studied in pediatric patients was the development of "gray baby syndrome" from chloramphenicol, an antibiotic (Ref. 6). After an initial report of 5 deaths and a subsequent report of 18 deaths in neonates, it was learned that the immature livers of these infants were unable to clear chloramphenicol from the body, allowing toxic doses of the drug to accumulate. Other cases in which inadequately studied drugs have resulted in serious adverse effects in pediatric patients include teeth staining from tetracycline, kernicterus from sulfa drugs, withdrawal symptoms following prolonged administration of fentanyl in infants and small children, seizures and cardiac arrest caused by bupivacaine toxicity, development of colonic strictures in pediatric cystic fibrosis patients after exposure to high-dose pancreatic enzymes, and hazardous interactions between erythromycin and midazolam (Refs. 7, 8, 9, 10, 11, 12, 13, 14, 15, and 16). Many such adverse reactions could be avoided if pediatric studies were conducted before drugs were widely used in pediatric patients.

Failure to conduct pediatric testing may, in unusual cases, deprive pediatric patients of significant therapeutic advances. Failure to develop a pediatric formulation of a drug, where younger pediatric populations cannot take the adult formulation, may also deny pediatric patients access to important therapeutic advances, or require pediatric patients to take the drug in homemade, poorly bioavailable formulations.

II. FDA Initiatives To Improve Pediatric Use Information

FDA has taken a number of steps in recent years to address inadequate pediatric drug testing and inadequate pediatric use information in drug labeling. Perhaps the most significant step was the issuance of the 1994 rule requiring drug manufacturers to survey existing data and determine whether those data are sufficient to support additional pediatric use information in the drug's labeling (59 FR 64240). Under the 1994 rule, if a manufacturer determines that existing data permit modification of the label's pediatric use information, the manufacturer must submit a supplemental new drug application (NDA) to FDA seeking approval of the labeling change. The

rule explicitly recognizes that controlled clinical studies to support pediatric use information need not have been carried out in pediatric patients where the course of the disease and the effects of the drug are sufficiently similar in children and adults to permit extrapolation from the adult effectiveness data to pediatric patients. In these cases, controlled clinical studies in adults together with pharmacokinetic and adverse reaction data in pediatric patients may be sufficient to establish pediatric safety and effectiveness.

Although the preamble to the 1994 rule recognizes FDA's authority to require drug manufacturers to conduct pediatric studies on a case-by-case basis, the rule does not impose a general requirement that manufacturers carry out studies if existing information is not sufficient to support pediatric use information. Instead, where there is insufficient information to support a pediatric indication or pediatric use statement, the rule requires the manufacturer to include in the drug's labeling the statement: "Safety and effectiveness in pediatric patients have not been established." Because the rule focuses on gathering existing information about pediatric use, rather than carrying out new studies, supplements filed in response to the rule will be for marketed drugs. The rule does not apply to products first entering the marketplace, except to the extent that pediatric studies conducted on such products before approval can take advantage of the rule's explicit authorization to rely on pharmacokinetic data rather than adequate and well-controlled studies in pediatric patients, and that labeling statements about pediatric use must conform to the rule's labeling requirements.

FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation (CBER) and Research have implemented a "Pediatric Plan" designed to focus attention on and encourage voluntary development of pediatric data both during the drug development process and after marketing. At specified points during the investigation of a new drug or biological product, FDA staff discuss with the sponsor the data needed to support pediatric labeling and encourage them to conduct needed studies. CDER and CBER have also begun to implement a program in which, after review of an NDA, biologics license application (BLA), or supplemental application, the FDA reviewer fills out a "pediatric page." The pediatric page does not itself

impose any requirements, but describes the adequacy of product labeling for pediatric patients and plans for further pediatric studies. If pediatric labeling is found to be inadequate, the pediatric page states whether additional pediatric studies are needed. If pediatric studies are needed, the pediatric page states whether the applicant has agreed to conduct the necessary studies and, if necessary, to develop a pediatric formulation. FDA is also developing a draft guidance document on pediatric pharmacokinetics.

In addition, FDA has taken steps to improve pediatric use information for marketed drugs under the pediatric plan. CDER has identified the 10 drugs most used in pediatric populations for which there is no pediatric use information or for which the pediatric use information is inadequate given the pattern of use in pediatric patients. The manufacturers of these drugs have been notified of the widespread use of their drugs in the pediatric population and asked to respond to the 1994 rule. CBER is currently identifying the biological products most frequently used in pediatric patients without labeling information. FDA has developed guidance to manufacturers on the content and format for pediatric use supplements under the 1994 rule and is tracking pediatric use supplements and commitments.

III. Results of Actions to Date and Need for Additional Steps

Although the actions taken by FDA to date have produced some gains in pediatric labeling, they have not yet substantially increased the number of drugs and biological products for which there is adequate pediatric use information. The percentage of new products entering the marketplace that contain adequate pediatric safety and effectiveness information has not shown consistent improvement in the last decade. An informal survey conducted by the American Academy of Pediatrics in 1990 found that of all new molecular entities (NME's) approved between 1984 and 1990, 20 percent had information on pediatric use. Not all NME's have usefulness in pediatric patients, however. For example, for NME's approved in the years 1991–1996, 53 percent were regarded by FDA as having potential usefulness in pediatric patients. Presumably, if only the NME's with usefulness in pediatric patients had been considered in the survey, the percentage with pediatric labeling would have been somewhat higher, and as high as 42 percent.

FDA compared the number of NME's approved in 1991 and 1996 with

potential usefulness in pediatric patients and looked at the adequacy of pediatric labeling for those drugs. Fifty-six percent (9/16) of the NME's approved in 1991 with potential usefulness in pediatric patients had some pediatric labeling at the time of approval. In 1996, only 37 percent (15/40) of the NME's with potential usefulness in pediatric patients had some pediatric labeling at the time of approval. (For both 1991 and 1996, those drugs counted as having pediatric labeling may not have been labeled for all age groups in which the drug was useful.) The manufacturers of an additional 17 drugs promised to conduct pediatric studies after approval. It is uncertain how many of these promises will result in pediatric labeling. Of the seven NME's approved in 1991 for which postapproval pediatric studies were promised, only one now has pediatric labeling.

These data indicate that voluntary efforts have, thus far, not substantially increased the number of products entering the marketplace with adequate pediatric labeling. Therefore, FDA has tentatively concluded that additional steps are necessary to ensure the safety and effectiveness of drug and biological products for pediatric patients. This proposed rule includes provisions that would require the manufacturers of certain new and marketed drugs and biological products to evaluate the safety and effectiveness of their products in pediatric patients, where existing information is not sufficient to support pediatric use labeling but the product is likely to be commonly used in pediatric patients, the product is a new drug or biological product which would provide a meaningful therapeutic benefit to pediatric patients over existing treatments, or the product is a marketed drug or biological product which is indicated for a very significant or life threatening illness.

Although this proposal would address the lack of pediatric labeling through the imposition of regulatory requirements, the agency solicits comment on whether there are other ways to assure that manufacturers reliably conduct pre- or postapproval studies in pediatric patients.

At the same time as it is issuing this proposed rule, FDA has initiated other actions that it hopes will encourage the development of adequate pediatric use information. FDA plans to develop guidance on clinical trial designs for assessing pediatric safety and effectiveness. The agency has also discussed with the pharmaceutical industry a policy on user fees for pediatric studies designed to encourage

the submission of these studies. Such a policy could be implemented through legislation at the time of reauthorization of the Prescription Drug User Fee Act of 1992. FDA has proposed that user fees be waived for supplements to add pediatric use labeling, unless the supplements contain adequate and well-controlled clinical trials. Thus, supplements that rely on pharmacokinetic data to extrapolate from existing adult studies would not be subject to user fees. FDA might also be prepared to waive the user fee for supplements containing pediatric use studies for which FDA granted a request to defer submission until after approval.

Finally, FDA has issued a policy statement describing the types of evidence necessary to support supplements. In that policy, FDA provides guidance to manufacturers on the circumstances in which FDA may approve a supplement in which confirmation of the results of an adequate and well-controlled trial is provided by information other than a second adequate and well-controlled trial precisely replicating the first trial, or by studies without the extensive documentation ordinarily required.

The agency believes that financial and other incentives to manufacturers, although largely beyond FDA's current authority, could further increase the number of drugs and biologics with adequate pediatric labeling.

IV. Public Hearing

Because of the importance of ensuring the safety and effectiveness of the medications administered to children and the need to address the absence of pediatric labeling in the most effective manner possible, FDA intends to hold a public hearing at which recognized experts in the field, members of the pharmaceutical industry, and other interested parties will have an opportunity to discuss the issues raised by this proposal.

V. Description of the Proposed Rule

The proposed rule is designed to ensure that new drugs and biological products that are likely to be commonly used in children or that represent a meaningful therapeutic benefit over existing treatments for children contain adequate pediatric labeling for the approved indications at the time of, or soon after, approval. The rule would therefore require a manufacturer of a drug classified as a "new chemical entity" or a new (never-before-approved) biological product to submit, before approval, safety and effectiveness information on relevant pediatric age groups for the claimed indications. The

submission of information could be deferred until after approval if, for example, pediatric studies should not begin until information on adults was collected, or where the collection and filing of pediatric data would delay the availability of a product that provides a significant therapeutic advantage to adults. The requirement would be waived for some or all pediatric age groups, if: (1) The product did not represent a meaningful therapeutic benefit over existing treatments for pediatric patients and was unlikely to be used in a substantial number of pediatric patients, (2) studies on the product were impossible or highly impractical because, for example, the population was too small or geographically dispersed, (3) the product were likely to be unsafe or ineffective in pediatric patients, or (4) reasonable efforts to develop a pediatric formulation (if one were needed) had failed.

The rule is also intended to assist in improving pediatric use information for already marketed drugs and biological products where there is a compelling need for more information. The rule would therefore codify FDA's authority, discussed in the 1994 rule, to require, in compelling circumstances, that manufacturers of already marketed drugs and biological products conduct studies to support pediatric use labeling for the claimed indications.

The proposed rule also contains provisions designed to encourage discussions of the need for pediatric studies early in the drug development process, as well as postmarketing reporting requirements designed to assist FDA in determining whether pediatric studies are needed for particular products and whether required studies are being carried out with due diligence.

FDA notes that the Federal Food, Drug, and Cosmetic Act (the act) authorizes FDA, under certain circumstances, to grant periods of exclusive marketing to manufacturers who obtain approval of labeling supplements adding pediatric use information to a drug's label. First, a manufacturer is entitled to 3 years of exclusive marketing under section 505(c)(3)(D)(iii) and (j)(4)(D)(iv) of the act (21 U.S.C. 355(c)(3)(D)(iii) and (j)(4)(D)(iv)) for obtaining approval of pediatric use labeling based on clinical studies, other than bioavailability studies. Second, a manufacturer may be entitled to 7 years of exclusive marketing under the Orphan Drug Amendments for obtaining approval of an application for use of a drug to treat a disease or condition affecting a

pediatric population of less than 200,000.

A. Scope

The proposed rule would cover only original applications for those drugs classified as "new chemical entities," including antibiotics, and new biological drug products that have never been approved for any indication. A "new chemical entity," defined in 21 CFR 314.108(a), is a drug that contains no previously approved active moiety. (An "active moiety," also defined in § 314.108(a), is the molecule or ion, excluding certain appendages, that is responsible for the physiological or pharmacological action of the drug.) New chemical entities and new biological products are generally the most innovative and therapeutically significant of the new drug products approved by FDA.

In an effort to limit the scope of the rule to those products for which pediatric labeling is most urgently needed and to minimize the burden on manufacturers and on agency resources available to review new product applications, FDA has tentatively concluded that the pediatric study requirement would not apply to subsequent applications for the drug or biological product, e.g. to supplements for new indications or dosage forms. FDA recognizes that, in some cases, a change to an approved product, particularly a new indication, may have clinically significant use in children. FDA seeks comment on whether the requirement should apply more broadly, e.g., to applications for minor chemical variations of approved products, new indications, new dosage forms or new routes of administration, and, if so, how the rule could be applied in a manner that does not impose undue burdens on manufacturers or agency resources.

The proposed rule would require an assessment of safety and effectiveness in one subpopulation (pediatric patients) only for the indications already claimed by the manufacturer. It would not require a manufacturer to study its product for unapproved ("off-label") indications, even if the product were widely used in pediatric patients for those indications. Although the proposed rule would not apply to unapproved pediatric indications, nothing in the rule would diminish the physician's power to prescribe drugs and biological products for such unapproved indications.

B. Not-Yet-Marketed Drug and Biological Products

1. Sections 312.23(a)(3)(v), 312.33(a)(8), and 312.47(b)(1)(i) and (b)(2) (21 CFR 312.23(a)(3)(v), 312.33(a)(8), and 312.47(b)(1)(i) and (b)(2))—Early Discussion of Plans for Pediatric Studies

In the development of a new drug or biological product, decisions about appropriate populations to study and the design of such studies must often be made well before the submission of an NDA or BLA. FDA has identified several critical points in the drug development process, before submission of an NDA or BLA, during which the sponsor and FDA should focus on the sponsor's plans to assess pediatric safety and effectiveness. These time points include: Any pre-investigational new drug application (IND) meeting or "end of phase 1" meeting for a drug designated under subpart E of part 312 (21 CFR part 312), the IND submission, the IND annual report, any "end of phase 2" meeting, the presentation of the IND to an FDA drug advisory committee, and any pre-NDA or pre-BLA meeting. Of these, the pre-IND meeting, the "end of phase 1" meeting, the IND submission, the IND annual report, the "end of phase 2" meeting, and the pre-NDA meeting are codified in part 312, FDA's regulations governing IND's.

FDA has already proposed to amend the IND annual report requirement to include discussion of pediatric studies (60 FR 46794, September 8, 1995). FDA is proposing to amend the remaining regulations to specify that these meetings and reports should include discussion of the assessment of pediatric safety and effectiveness. To assist manufacturers in planning for studies that may be required under this proposed rule, FDA is also proposing to inform manufacturers at the "end of phase 2" meeting, or at the earliest appropriate opportunity, of the agency's best judgment, at that time, of the pediatric studies that will be required for the product and when the studies should be submitted.

In addition to the discussions of pediatric testing codified in this proposed rule, FDA will also assist manufacturers by providing early consultations on chemistry and formulation issues raised by requirements under this rule.

2. Sections 314.50(g)(1) and 601.27—Required Studies

Under proposed §§ 314.50(g) and 601.27(a), an original application for a drug classified as a new chemical entity or an application for a new biological

product would be required to contain data adequate to assess the safety and effectiveness of the drug product for all pediatric age groups for the claimed indications, unless FDA granted a deferral or full or partial waiver of the requirement. Assessments required under this section for a product that represented a meaningful therapeutic benefit over existing treatments would have to be carried out using appropriate formulations for the age group(s) for which the assessment is required (see "Pediatric Formulations," in section V.E of this document), unless reasonable efforts to produce a pediatric formulation had failed (see "Waivers," in section V.B.4 of this document).

The proposed rule does not mandate particular types of studies. The sponsor should consult with FDA on the types of data that will be considered adequate to assess pediatric safety and effectiveness. As described in the 1994 final rule, gathering adequate data to establish pediatric safety and effectiveness may not require controlled clinical trials in pediatric patients. Where the course of the disease and the product's effects are similar in adults and children, FDA may conclude that pediatric safety and effectiveness can be based on adult effectiveness data together with pharmacokinetic and safety data in pediatric patients. The proposed rule also does not necessarily require separate studies in pediatric patients. In appropriate cases, adequate data may be gathered by including pediatric patients as well as adults in the original studies conducted on the product.

3. Sections 314.50(g)(2), 314.81(b)(2)(vii), and 601.27(b)—Deferred Submission and Postmarketing Reports

In some cases, pediatric testing should not begin until certain safety and/or effectiveness information in adults has been collected. FDA believes that in certain cases it may be appropriate to defer submission of pediatric studies. For example, in such cases, an NDA or biological product license could be ready for approval for adult use before pediatric studies were completed. Also, where a product was needed to treat a serious or life-threatening disease for which there were not satisfactory alternative therapies or where the product represented a meaningful therapeutic benefit over existing therapies, it would be contrary to the public health to delay approval until pediatric studies were submitted.

Proposed §§ 314.50(g)(2) and 601.27(b) would permit FDA to defer the submission of some or all of the

required pediatric data until after approval of the product for adult use, on its own initiative or at the request of the applicant. If the applicant requested deferral, the request would be required to contain an adequate justification for delaying pediatric studies. If FDA concluded that there were adequate justification for deferring the submission of pediatric use studies, the agency could approve the product for use in adults subject to a requirement that the applicant submit the required pediatric studies within a specified time after approval. FDA would consult with the sponsor in determining a deadline for the deferred submission, but would ordinarily require the submission not more than 2 years after the date of the initial approval. The deadline for submission of studies would take account of likely or actual difficulties encountered in recruiting pediatric patients to the study. FDA seeks comment on the circumstances in which FDA should permit deferral. FDA also seeks comment on factors that should be considered in determining whether a product is among those that should be studied in adults before children.

To ensure that deferral would not unnecessarily delay the submission of pediatric use information, FDA has tentatively concluded that a request for deferred submission should include a description of the planned or ongoing pediatric studies, and evidence that the studies were being or would be conducted: (1) With due diligence, and (2) at the earliest possible time. To permit FDA to monitor the conduct of postapproval studies to ensure that they were carried out with due diligence, FDA is proposing to amend § 314.81(b)(ii) of the postmarketing reports requirements to require applicants to include in their annual reports whether they have been required to conduct postmarket pediatric studies and, if so, to report the status of those studies. (Additional postmarketing reporting requirements are described under "Remedies," in section V.G of this document.) FDA seeks comment on the types of evidence FDA should examine to ensure that deferred studies are carried out in a timely fashion.

4. Sections 314.50(g)(3) and 601.27(c)—Waivers

FDA does not intend to require pediatric assessments unless the product represents a meaningful therapeutic benefit over existing treatments or is expected to be widely used in pediatric patients. FDA also does not intend to require pediatric assessments in other situations where the study(ies) necessary to carry out the

assessment are impossible or highly impractical or would pose undue risks to pediatric patients. Thus, §§ 314.50(g)(3) and 601.27(c) would require FDA to grant a waiver of the pediatric study requirement on its own initiative or at the request of the applicant if: (1) The product (a) did not represent a meaningful therapeutic benefit over existing treatments, and (b) was not likely to be used in a substantial number of pediatric patients as a whole, or was not likely to be used in a substantial number of one or more pediatric subpopulations, or (2) necessary studies were impossible or highly impractical, because, for example, the number of such patients was so small or geographically dispersed, or (3) there were evidence strongly suggesting that the product would be ineffective or unsafe in some or all pediatric populations. If a waiver were granted because there was evidence that the product would be ineffective or unsafe in pediatric patients, this information would be included in the product's labeling.

An applicant could request a full waiver of all pediatric studies if one or more of the grounds for waiver applied to the pediatric population as a whole. A partial waiver permitting the applicant to avoid studies in particular pediatric age groups could be requested if one or more of the grounds for waiver applied to one or more pediatric age groups. In addition to the other grounds for waiver, the proposed rule would authorize FDA to grant a partial waiver for those age groups for which a pediatric formulation was required (see "Pediatric Formulations," in section V.E of this document), if reasonable attempts to produce a pediatric formulation had failed.

The proposed rule would require the applicant to include in the request for a waiver an adequate justification for not providing pediatric use information for one or more pediatric populations. For example, the waiver request could demonstrate that the product was indicated for a disease that does not occur in a substantial number of pediatric patients (e.g., drugs for breast or prostate cancer). The waiver request could demonstrate that the product was a member of a drug class known to be unsafe in specific pediatric age groups (e.g., chloramphenicol, an antibiotic, which has caused serious adverse events in neonates. Also, it is widely known that, except for serious or life threatening diseases where alternative therapy is needed, quinolones, anti-malarial agents, are not recommended in young children due to concerns about cartilage and bone development).

Animal toxicity data or immature metabolic pathways for newborns are examples of data that may be used to demonstrate that the product was a member of a drug class known to be unsafe in specific pediatric age groups.

FDA would grant the waiver request if the agency found that there was a reasonable basis on which to conclude that any of the grounds for a waiver had been met. A full waiver would be appropriate where, for example, the product did not represent a meaningful therapeutic advance and was not likely to be used in a substantial proportion of any pediatric age group. A partial waiver would be appropriate where, for example, the product was likely to be used in substantial numbers in some pediatric age groups but not others, where the product was likely to be unsafe or ineffective in some age groups, or where reasonable efforts to develop a pediatric formulation necessary for some age groups had failed. If a waiver were granted on the ground that it was not possible to develop a pediatric formulation, the waiver would cover only those pediatric age groups requiring a pediatric formulation.

The agency solicits comments on the proposed grounds for waiving the pediatric study requirement and whether additional grounds may exist, such as whether cost should justify waiver of the pediatric study requirement. Additionally, FDA seeks comment on defining the term "meaningful therapeutic benefit". Comment is also requested on, what should be considered a "substantial number" of pediatric patients, i.e., how the agency should establish a level of expected use in pediatric patients below which pediatric labeling would not be required for a drug that did not represent a meaningful therapeutic advance. FDA is considering two possible methods. The first method would focus on the number of times the drug was expected to be used in pediatric patients, annually. Under this method, FDA has tentatively concluded that 100,000 or more prescriptions or uses per year in all pediatric age groups would be considered a substantial number. Products that might require studies under this test include anesthetics, anticonvulsants, asthma drugs, antidepressants, antimicrobials and antivirals, vaccines, and drugs to treat certain skin conditions. FDA has also tentatively concluded that a partial waiver for a particular pediatric age group would be available under this method if the product were expected to be prescribed or used fewer than 15,000 times per year in that age group.

The second possible method for establishing the level of expected use would focus on the number of pediatric patients affected by the disease or condition for which the product is intended. Physician mention data from the IMS National Disease and Therapeutic Index¹, shows pediatric use of certain products generally falling within two ranges (i.e., those products either exceeding 100,000 physician mentions for pediatric use per year or those falling below 15,000 physician mentions for pediatric use per year. Thus, under this method, FDA has tentatively concluded that 100,000 pediatric patients affected by the disease or condition for which a product was indicated would be considered a "substantial number" of pediatric patients. A partial waiver for a particular pediatric age group would be available under this method if fewer than 15,000 patients in that age group were affected by the disease or condition. FDA seeks comment on these methods of assessing expected pediatric exposure and on the specific numerical thresholds suggested.

5. Section 314.50(d)(7)—Pediatric Use Section of Application

Under proposed § 314.50(d)(7), applicants would be required to include in their applications a section summarizing and analyzing the data supporting pediatric use information for the claimed indications. The proposed new section of the application would contain an integrated summary of the clinical pharmacology studies, controlled clinical studies, uncontrolled clinical studies, or other data or information that are relevant to the safety and effectiveness, and benefits and risks of the drug in pediatric populations. Because full descriptions of all such studies must already be provided under § 314.50 (d)(3) and (d)(5), the new pediatric use section would be required to contain only brief summaries of the studies together with a reference to the full description of each provided elsewhere in the application.

C. Marketed Drug and Biological Products

1. Section 201.23—Required Studies

As discussed in the preamble to the 1994 rule, FDA has the authority, under certain circumstances, to require the manufacturers of marketed drugs that are used in pediatric patients to submit pediatric studies assessing safety and effectiveness for the already approved

indications (59 FR 64240 at 64243). Proposed § 201.23 would authorize FDA to require a manufacturer of a marketed drug or biological drug product to submit an application containing data evaluating the safety and effectiveness of the product in pediatric populations, in compelling circumstances. FDA has tentatively concluded that it should impose such a requirement only where the agency made one of two findings that: (1) The product was widely used in pediatric populations and the absence of adequate labeling could pose significant risks to pediatric patients; or (2) the product was indicated for a very significant or life threatening illness, but additional dosing or safety information was needed to permit its safe and effective use in pediatric patients.

Before requiring a study under § 201.23, the appropriate center, CDER or CBER, would consult with the manufacturer on the type of studies needed and on the length of time necessary to complete them and would notify the manufacturer, by letter, of the center's tentative conclusion that such a study was needed and provide the manufacturer an opportunity to provide a written response and to have a meeting with the center. At the center's discretion, such a meeting could be an advisory committee meeting. If, after reviewing any written response and conducting any requested meeting, CDER or CBER determined that additional pediatric use information were necessary, the center director would issue an order requiring the manufacturer to submit a supplemental application containing pediatric safety and effectiveness data within a specified time. The manufacturer would be able to request reconsideration by the Commissioner for Food and Drugs (the Commissioner) of the order under the provisions at 21 CFR 10.33.

Proposed § 201.23(c) would require FDA to grant full or partial waivers of study requirements on their own initiative or at request of the applicant for reasons analogous to those which would entitle not-yet-marketed drug and biologic products to waivers.

FDA seeks comment on whether it should codify its authority to require the manufacturers of marketed drugs to conduct pediatric studies, and, if so, the circumstances under which the agency should exercise that authority. The agency also solicits comment on the proposed grounds for waiving the pediatric study requirement for already marketed drug and biological products and whether additional ground may exist, such as whether cost should justify waiver of the pediatric study requirement. Comment is also sought on

¹IMS, National Disease and Therapeutic Index, IMS America; Plymouth Meeting, PA.

defining the term "very significant illness".

D. Studies in Different Pediatric Age Groups

Because the pharmacokinetics and pharmacodynamics of a drug or biological product may be different in different pediatric age groups or stages of development, it could be necessary to conduct studies in more than one pediatric age group. The following age categories for the pediatric population are commonly distinguished: (1) Neonates; (2) infants; (3) children, and (4) adolescents. In the 1994 rule, FDA defined neonates as birth up to 1 month, infants as 1 month to 2 years, children as 2 years to 12 years, and adolescents as 12 years to 16 years (59 FR 64242). The need for studies in more than one age group would depend on whether the drug or biological product was likely to be used in each age group (see "Waivers," in sections V.B.4 and V.C.1 of this document) and whether safety and effectiveness in one age group could be extrapolated to other age groups. The metabolism and elimination of the drug and the stage of development of the child may be important in determining which age groups should be tested. There would generally need to be sufficient data, including pharmacokinetic data to establish dosing and safety for each group. (Pharmacokinetic data are generally collected from pediatric patients receiving the drug or biologic as treatment rather than from healthy children.) In cases where the product was expected to have similar pharmacokinetics in more than one age group, pharmacokinetic data from one age group could be sufficient to support labeling for other age groups. Such extrapolation would not be routine.

FDA recognizes that studies in neonates and young infants present special problems. On one hand, failure to adequately test drugs in this age group has led to both under treatment and, conversely, some of the most serious therapeutic mishaps known to have occurred among pediatric patients. On the other hand, studies in this age group may be significantly more difficult to carry out in the period before or soon after approval than studies in older age groups. However, FDA recognizes that for some conditions, early study would be advantageous. FDA would therefore expect to apply the study requirement to patients in this age group with caution and would, whenever appropriate, permit such studies to occur after the product has been successfully studied in older children. The agency seeks comment on

the issues raised by requiring studies in this age group.

E. Pediatric Formulations

In some cases, testing of a product in pediatric patients could require the development of a pediatric formulation. Many children below a certain age are unable to swallow pills and may require a liquid, chewable or injectable form of the product. The need to develop a pediatric formulation does not necessarily mean that the product would not have been used in children in its adult dosage form. In many cases, physicians prescribing tablets to young children direct the parent to grind up the tablet and sprinkle the powder into the child's food. In other cases, pharmacists may compound tablets into pediatric formulations of their own choosing. These methods of administering adult dosage forms to children may be unsatisfactory, however, because the bioavailability of any particular product in this form is untested and dosing may be highly variable. A standardized pediatric formulation ensures bioavailability and consistency of dosing, and permits meaningful testing of safety and effectiveness.

FDA has tentatively concluded that it would be reasonable to expect a manufacturer of a product to produce a pediatric formulation, if one were necessary, only in those cases where a new drug or new biological product provided a meaningful therapeutic benefit over existing treatments, and where the study requirement had not been waived in the age group requiring the pediatric formulation. Proposed §§ 201.23, 314.50(g)(1) and 601.27(a) contain this requirement. The type of formulation needed would vary depending on the age group in which the product were to be used and the disease being treated. Young children unaccustomed to taking drugs may need liquid or chewable formulations, while children with serious and chronic diseases may need only smaller tablets. The difficulty and cost of producing a pediatric formulation may vary greatly depending upon such factors as solubility of the compound and taste. FDA would waive the requirement for pediatric studies (see "Waivers," in section V.B.4 of this document) in age groups requiring a pediatric formulation, if the manufacturer provided evidence that reasonable attempts to produce a pediatric formulation had failed.

FDA solicits comment on whether it is appropriate to require a manufacturer to develop a pediatric formulation and, if so, the circumstances in which it

would be appropriate to impose such a requirement. For example, should the cost of developing a pediatric formulation justify a waiver of the pediatric study requirement? Should the number of patients affected by the disease or condition in the relevant age group be considered in determining whether to require the development of a pediatric formulation for that age group? Is it appropriate to ask the manufacturer of a not-yet-approved product to allocate resources to developing pediatric formulation(s)? Where cost is a significant issue, would it be appropriate to defer development of a pediatric formulation until after approval of the product? What should be considered "reasonable attempts" to develop a pediatric formulation?

As noted above, FDA was unable to quantify the potential benefits of this rule due to the unavailability of relevant data and studies. Nevertheless, the agency will attempt to assess the benefits of the final rule and solicits comment on the appropriate design and methodology of such measurement. In particular, FDA seeks information and data that would help the agency to: (1) Quantify the societal costs of the adverse drug events experienced by pediatric populations and (2) assess the proportion of these adverse drug events that would be eliminated by the new information that would result from the rule. In addition, FDA seeks information and data that would help the agency to: (1) Quantify the societal costs of the underused or inadequate drug therapies prescribed to pediatric populations and to (2) assess the proportion of these costs that would be eliminated by the new information that would result from the rule.

F. Ethical Issues

Ethical concerns may have contributed to reluctance to conduct studies in pediatric patients. To address these concerns, both the American Academy of Pediatrics (Ref. 1) and the Department of Health and Human Services, 45 CFR part 46, subpart D, have developed guidelines or regulations for the ethical conduct of clinical studies in pediatric patients. Because pediatric patients represent a vulnerable population, special protections are needed to protect their rights and to shield them from undue risk. As the American Academy of Pediatrics has observed, however, administration of untested drugs "may place more children at risk than if the drugs were administered as part of well-designed, controlled clinical trials" (Ref. 1 at p. 286). The ethical guidelines currently in place are designed to

protect children's rights and protect them from undue risk. Sponsors should adhere to these guidelines for pediatric studies conducted under this rule. The agency seeks comment on ethical issues that may be raised by this proposal.

G. Remedies

FDA has tentatively concluded that the most practical remedy for failure to submit a required study is an injunctive action brought under the "misbranding" or "new drug" provisions of the act. Denying or withdrawing approval of an otherwise safe and effective drug or biological product is not a satisfactory remedy, because removal of a product from the marketplace could deprive other patients of the benefits of a useful medical product. FDA does not intend to deny or withdraw approval of a product for failure to conduct pediatric studies, except possibly in rare circumstances.

If a manufacturer failed, in the time allowed, to submit adequate studies to evaluate pediatric safety and effectiveness, under proposed §§ 201.23(d) or 314.50(g), FDA could consider the product misbranded under section 502 of the act (21 U.S.C. 352) or an unapproved new drug under section 505(a) of the act (see "Legal Authority," in section VI of this document). When a product is misbranded or an unapproved new drug, sections 302, 303, and 304 of the act (21 U.S.C. 332, 333, and 334) authorize injunction, prosecution or seizure. For violations of this rule, should it become final, FDA would ordinarily expect to file an enforcement action for an injunction, asking a Federal court to require the company to submit an assessment of pediatric safety and effectiveness for the product. Violation of the injunction would result in a contempt proceeding or such other penalties as the court ordered, e.g., fines.

To assist FDA in determining whether pediatric assessments are needed or are being carried out with due diligence, FDA is proposing to amend § 314.81 (other postmarketing reports) to require that annual reports filed by the manufacturer contain information on labeling changes that have been initiated in response to new pediatric data, analysis of clinical data that have been gathered on pediatric use, assessment of data needed to ensure appropriate labeling for the pediatric population, and information on the status of ongoing pediatric studies. Where possible, the annual report would also contain an estimate of patient exposure to the drug product, with special reference to the pediatric population.

FDA seeks comment on appropriate remedies for failure to conduct a required pediatric study and the circumstances, if any, in which the agency should deny or withdraw approval of a drug product.

VI. Legal Authority

Therapeutic tragedies in pediatric patients have prompted some of the most important federal legislation to ensure that drugs are safe and effective. For example, the act was enacted in 1938 in the wake of a tragedy in which many pediatric patients died after taking an untested medicine called Elixir of Sulfanilamide. The legislative history of this enactment demonstrates that Congress intended to ensure that children, as well as adults, received adequately tested and appropriately labeled drugs. (See, e.g., 78 Congressional Record 567-573 (1934) (statement of Sen. Copeland).)

Every mother is anxious that the food and medicine given her baby shall be above suspicion. The welfare of every man, woman, and child is involved in the quality and preparation of the foods and drugs sold in America * * *. [T]he purpose of this legislation * * * is to protect the public, to protect the mothers and the children * * * 81 Congressional Record 7312 (1937) (remarks of Rep. Coffee)

The agency has stated, in the context of both pediatric studies and studies in women, that an application for marketing approval should contain data on a reasonable sample of the patients likely to be given a drug or biological product once it is marketed (59 FR 64240 at 64243; 58 FR 39406 at 39409, July 22, 1993). The agency has further stated that in some cases it could require studies in pediatric patients and in women for both not-yet-approved products and marketed products (*Id.*).

The primary rationale for such a requirement is the same for women and pediatric patients. In most cases, drugs and biological products behave similarly in demographic subgroups, including age and gender subgroups, even though there may be variations among the subgroups, based on, for example, differences in pharmacokinetics. Thus, where a drug or biological product is indicated for a disease suffered equally by men, women, and children, and is not contraindicated in women or pediatric patients, the product will be widely prescribed for all three subgroups even if it were studied only in, or labeled only for, men. As described above, there is extensive evidence that many drugs labeled only for adult use are in fact widely used in pediatric patients for the same indications.

FDA notes that this proposal addresses only use of drug products for their approved indications in a significant subpopulation. The proposed rule does not address "off-label" or unapproved uses of approved drugs and biological products, in which an approved product is used for diseases or conditions other than those in the label. This rule would apply only where a product was expected to have clinically significant use in pediatric populations for the indications already claimed by the manufacturer.

In addition to the provisions cited below as authority for the proposed rule, the agency relies on section 701(a) of the act (21 U.S.C. 371(a)), which authorizes FDA to issue regulations for the efficient enforcement of the act.

A. New Drug and Biological Products

Biological drug products are subject both to section 351 of the Public Health Service Act (the PHS Act) and to the provisions of the act and implementing regulations applicable to drugs, except that manufacturers of biological products covered by approved BLA's are not required to submit NDA's under section 505 of the act. References to "drugs" in the following sections include biological drugs.

1. Sections 502(a), 502(f), 505(d)(7), and 201(n) of the Act

A drug is misbranded under section 502(a) of the act if its labeling is "false or misleading in any particular." Similarly, a new drug application must contain labeling that is not false or misleading (section 505(d)(7) of the act). Section 201(n) of the act (21 U.S.C. 321(n)) defines labeling as misleading if it "fails to reveal facts material * * * with respect to consequences which may result" not only from use of the product as labeled, but "from the use of the [product] * * * under such conditions of use as are customary or usual." Information on dosing and adverse effects are facts "material" to the consequences that may result from customary use in pediatric patients. A drug product is misbranded under section 502(f) of the act, if its label fails to provide adequate directions for each intended use. 21 CFR 201.5 states that adequate directions must be provided for each use recommended in the labeling and each use "for which the drug is commonly used." Thus, FDA may require a product to carry labeling that provides safety and effectiveness information on use in subpopulations in which the product is customarily or commonly used.

There is extensive evidence that drugs for diseases that affect both adults and pediatric patients are routinely used in pediatric patients despite the absence of pediatric labeling, and even in the face of disclaimers stating that safety and effectiveness have not been established in children. FDA may therefore consider pediatric use to be "customary or usual" or "commonly used" where the drug is indicated for a disease or condition that affects both adults and children, and the drug is not contraindicated in pediatric patients. In many cases, the use in pediatric patients of a drug labeled only for adults will increase over time, as physicians become aware of the drug's potential usefulness in children and familiar with the drug's uses and effects. Thus, FDA may conclude that a drug that was appropriately labeled for adult use at the time of approval is, at some later date, no longer appropriately labeled.

2. Sections 201(p), 301(a), and 505(a) of the Act

Under section 301 (a) and (d) of the act (21 U.S.C. 331 (a) and (d)) and section 505(a) of the act, a drug product is subject to enforcement action if it is a "new drug" for which no NDA has been approved. A product is a new drug under section 201(p) of the act if it is not recognized to be safe and effective under the conditions "prescribed, recommended, or suggested" in the drug's labeling. There is widespread evidence that, despite the absence of pediatric labeling, drugs are routinely used in pediatric patients for the labeled indications. FDA may therefore consider pediatric use to be "suggested" in a drug's labeling where the drug is indicated for a disease or condition that affects both adults and pediatric patients, unless the drug is specifically contraindicated for pediatric patients. As described above, because pediatric use of new drugs often increases over time, FDA may conclude that labeling that is appropriate at the time of approval is later no longer appropriate.

3. Section 502(j) of the Act

Section 502(j) of the act defines as misbranded those drugs that are dangerous to health when used in the manner prescribed, recommended, or suggested in their labeling. FDA may consider pediatric use to be "suggested" in a drug's labeling where the drug is indicated for a disease or condition that affects both adults and pediatric patients, unless the drug is specifically contraindicated for pediatric patients. As described earlier in this notice, the absence of pediatric testing and labeling poses risks to children including the

risk of unanticipated adverse reactions, and under- and over-dosing.

4. Section 505 (i) and (k) of the Act

Section 505(i) of the act that authorizes the issuance of regulations governing the use of investigational drugs, and the proviso in 505(k) of the act, which requires regulations issued under 505(i) to have "due regard * * * for the interests of patients," together authorize FDA to impose conditions on the investigation of new drugs, including conditions related to the ethics of a proposed investigation and to the interests of patients. Fairness in distribution of the burdens and benefits of research is one of the ethical principles underlying federal regulations on investigational drugs. (See, e.g., 44 FR 23192 at 23194, April 18, 1979 ("Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research").) Because exclusion of pediatric patients from clinical trials may deny them an equitable share of the benefits of research, section 505 (i) and (k) authorize FDA to require their inclusion in clinical trials.

5. Section 351 of the Public Health Service Act

Section 351 of the PHS Act (42 U.S.C. 262) provides authority to regulate the labeling and shipment of biological products. Under section 351(d), licenses for biological products are to be issued only upon a showing that they meet standards "designed to insure the continued safety, purity, and potency of such products" prescribed in regulations. The "potency" of a biological product includes its effectiveness (21 CFR 600.3(s)).

B. Marketed Drug Products

1. Section 502(f) of the Act and 21 CFR 201.5

A drug product is misbranded under section 502(f) of the act, if its label fails to provide adequate directions for each intended use. 21 CFR 201.5 states that adequate directions must be provided for each use recommended in the labeling and each use "for which the drug is commonly used." Where there is evidence that a drug product is widely used in pediatric patients, failure to provide adequate directions for the use could misbrand the product.

2. Sections 502(a) and 201(n) of the Act

A drug is misbranded under section 502(a) of the act if its labeling is false or misleading. Section 201(n) of the act defines labeling as misleading if it fails to reveal facts that are material in light of the consequences of the customary or

usual use of the product. Where a drug is widely used in pediatric patients, FDA may consider pediatric use to be "customary." Failure to provide adequate information on dosing and adverse effects in the pediatric population could render the product misbranded, even where the manufacturer does not promote the product for that subpopulation.

3. Section 502(j) of the Act

Section 502(j) of the act defines as misbranded those drugs that are dangerous to health when used in the manner prescribed, recommended, or suggested in their labeling. FDA may consider pediatric use to be "suggested" in a drug's labeling where the drug is indicated for a disease or condition that affects both adults and pediatric patients, unless the drug is specifically contraindicated for pediatric patients. As described earlier in this notice, the absence of pediatric testing and labeling poses risks to children including the risk of unanticipated adverse reactions, and under- and over-dosing.

4. Section 505(k) of the Act

Section 505(k) of the act authorizes FDA to order the holder of an approved NDA to submit reports of data necessary to determine whether there are grounds to withdraw approval of the NDA. FDA has in the past issued regulations under section 505(k) of the act (formerly section 505(j) of the act) requiring postapproval studies of certain drugs (see, e.g., 21 CFR 310.303 ("Continuation of long-term studies, records, and reports on certain drugs for which new drug applications have been approved")(1972); 21 CFR 310.304 ("Drugs that are subjects of approved new drug applications and that require special studies, records, and reports")(1972); and 21 CFR 310.500 ("Digoxin products for oral use; conditions for marketing")(1974)). Section 505(k) of the act also authorizes the agency to require other postmarketing reports on drug products.

5. Section 351 of the Public Health Service Act

Section 351(d) of the PHS Act authorizes FDA to ensure the "continued safety, purity, and potency" of biological products. Section 351(b) of the PHS Act prohibits false labeling of a biological product.

VII. Implementation Plan

All applications for drug and biological products covered by the final rule would be required to contain an assessment of pediatric safety and effectiveness for the claimed

indications, unless the applicant has obtained a waiver or deferral of this requirement from FDA.

FDA proposes that the final rule become effective 90 days after the date of its publication in the **Federal Register**. For new drug and biologic product applications submitted before the effective date of the final rule, the agency proposes a compliance date of 21 months after the effective date of the final rule. For new drug and biologic product applications submitted on or after the effective date of the final rule, the agency proposes a compliance date of 15 months after the effective date of the final rule. The agency solicits comments on the proposed effective date and proposed compliance dates.

VIII. 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 of the information collection provisions are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions,

searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Pediatric Safety and Effectiveness Reporting Requirements for Certain Drugs and Biological Products.

Description: FDA is proposing reporting requirements that include: (1) Reports on planned pediatric studies in investigational new drug applications (IND's) (proposed § 312.23(a)(10)(iii)); (2) Reports assessing the safety and effectiveness of certain drugs and

biological products for pediatric use in new drug applications (NDA's) and biologic license applications (BLA's) or in supplemental applications (proposed § 314.50(g)(1)); (3) Analyses of data on pediatric safety and effectiveness in NDA's (proposed § 314.50(d)(7)); (4) Postmarketing reports of analyses of data on pediatric safety and effectiveness (proposed § 314.81(b)(2)(vi)(C)); (5) Postmarketing reports on patient exposure to certain marketed drug products, analyzed and age (proposed § 314.81(b)(2)(i)); (6) Postmarketing reports on labeling changes initiated in response to new pediatric data (proposed § 314.81(b)(2)(vi)(C)); and (7) Postmarketing reports on the status of required postapproval studies in pediatric patients (proposed § 314.81(b)(2)(vii)). The purpose of these reporting requirements is to address the lack of adequate pediatric labeling of drugs and biological products by requiring the submission of evidence on pediatric safety and effectiveness for products with clinically significant use in children.

Description of Respondents: Sponsors and manufacturers of drugs and biological products.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

CFR section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
201.23	2	1	2	16	32
314.50(d)(7)	150	1	150	8	1,200
314.50(g)(1)	10	1	10	16	160
314.50(g)(2)	9	1	9	8	72
314.50(g)(3)	15	1	15	8	120
314.81(b)(2)(i)	625	1	625	1.5	937.5
314.81(b)(2)(vi)(c)	625	1	625	1.5	937.5
314.81(b)(2)(vii)	625	1	625	1.5	937.5
601.27(a)	1	1	1	16	16
601.27(b)	1	1	1	16	16
601.27(c)	1	1	1	16	16
Total:					4,444.5

There are no capital or operating and maintenance costs associated with this collection of information.

The agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection by September 15, 1997 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.

IX. Environmental Impact

The agency has determined under 21 CFR 25.24 (a)(8), (a)(11), and (e)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order

12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act (Pub. L. 104–4). 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). Under the Regulatory Flexibility Act, unless an agency certifies that a rule will not have

a significant economic impact on a substantial number of small entities, the agency must analyze regulatory options that would minimize the impact of the rule on small entities. The Unfunded Mandates Reform Act (Pub. L. 104-4) (in section 202) requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation).

The agency has reviewed this proposed rule and has determined that the proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, and these two statutes. This proposal is a significant regulatory action as defined by the Executive Order due to the novel policy issues it raises. With respect to the Regulatory Flexibility Act, the Commissioner certifies that the rule will not have a significant economic impact on a substantial number of small entities. Since the proposed rule does not impose any mandates on State, local, or tribal governments, or the private sector that will result in an annual expenditure of \$100,000,000 or more, FDA is not required to perform a cost-benefit analysis according to the Unfunded Mandates Reform Act.

A. Purpose

The FDA is proposing that a limited class of important new drugs and biologicals that are likely to be used in pediatric patients contain sufficient data and information to support directions for this use. As the approved labeling for many of these new products lack relevant pediatric information, any use in children greatly increases the risk of inappropriate dosing, unexpected adverse effects, and suboptimal therapeutic outcomes. The proposed rule is designed to ensure that new drugs, including biological drugs, that are therapeutically important and/or likely to be widely used in children contain adequate pediatric labeling at the time of, or soon after, approval.

B. Number of Affected Products and Required Studies

Neither the precise number of new drugs that would require additional pediatric studies nor the cost of these studies can be predicted with certainty. To develop plausible estimates, FDA examined the pediatric labeling status at time of approval for each NME and important biological approved from 1991 to 1995, and used these estimates to project the cost that would have occurred had the proposed rule been in

place over that period. The agency assumes that future costs would be reasonably similar. As shown in Table 2, each new drug was assigned to one of three categories: (1) Therapeutically important, some potential pediatric use, (2) other approvals, potential for wide pediatric use, and (3) all other approvals. (The first two categories include all products that the agency believes would have met the therapeutic importance and pediatric use threshold criteria set forth in this proposed rule. The third category includes all products that would not have met these criteria.) For NME's, these category assignments were based on pediatric pages completed by CDER's reviewing division at the time of each approval, the priority review designation for each drug, and physician mention data from the IMS National Disease and Therapeutic Index.² All priority NME's were assumed to be therapeutically important, and assigned to the first category, unless the drug's pediatric page specifically noted a low potential for pediatric use or the IMS data indicated no pediatric use. For nonpriority NME's, FDA assumed that wide pediatric use would have been expected for only those products that exceeded 100,000 physician mentions for pediatric use during 1995. Assessments of therapeutic importance for biologicals were developed retrospectively by CBER.

As shown, 60 of the 142 approvals (42 percent) over this 5-year period fell into the first two categories; that is, 47 drugs were classified as therapeutically important with at least some potential pediatric use and 13 less therapeutically important drugs were designated as offering a potential for wide pediatric use based on physician mentions. The 82 drugs (58 percent) grouped under the third category would presumably not have met the therapeutic importance and pediatric use criteria of the proposed rule.

TABLE 2.—ESTIMATED NUMBER OF NME'S AND BIOLOGICALS APPROVED IN 1991-95

[That Would Have Been Affected by the Proposed Rule]

Pediatric labeling status	Number of approved drugs	Percent of approved drugs
Therapeutically important, some potential pediatric use	47	33
Some pediatric labeling	16	
No pediatric labeling	31	
Other approvals, potential for wide pediatric use	13	9
Some pediatric labeling	7	
No pediatric labeling	6	
Subtotal	60	42
Some pediatric labeling	23	
No pediatric labeling	¹ 37	
All other approvals	82	58
Total Approvals	142	100

¹ Pediatric page shows seven ongoing pediatric studies.

In assessing the amount of additional research that would have been required for the 60 drugs from the first two categories (those that would have potentially been affected by the proposed rule), FDA believes that most would not have required extensive additional clinical trials. As FDA explained in the 1994 final rule (59 FR 64240), extrapolations from adult effectiveness data based on pharmacokinetics studies and other safety data can be sufficient to provide the necessary dosing pediatric information for those drugs that work by similar mechanisms in adults and children. The agency estimates that the majority of these 60 drugs could, to some extent, rely on such extrapolations. Although the proposed rule identifies four pediatric subgroups: (1) Neonates, (2) infants, (3) children, and (4) adolescents, the need for studies in more than one age group depends on the likely use of the drug in each age group and on whether relevant data can be extrapolated to other age groups. As a rule, individual clinical trials would rarely be required for each age group for a given drug.

Estimates of the size of the studies that would have been required to support pediatric labeling for these 60 drugs vary from 20 patients where the simplest type of pharmacokinetic study

² IMS, National Disease and Therapeutic Index, IMS America; Plymouth Meeting, PA. FDA's analysis does not include data from 1996 because the IMS data are not yet available.

would be adequate, to 70 to 120 pediatric patients for studies where some safety and effectiveness data would be needed, to several hundred pediatric patients for studies where more substantial safety and effectiveness data would be required. Thus, for the purpose of developing order-of-magnitude cost estimates, FDA further subdivided the 60 potentially affected drugs into three distinct groupings. The first group of 30 drugs would have required the least amount of new data and includes both the 7 drugs for which the CDER pediatric pages indicate that pediatric trials were already underway and the 23 drugs that already had at least some pediatric labeling at the time of approval. Based on a review of those labels at approval time, FDA estimated that up to half, or 15 of these 30 drugs may have needed limited additional data that would have involved new studies with, on average, 50 pediatric patients each.

Next, FDA assumed that 23 drugs (about three quarters of the remaining 30) would have required new pediatric studies with data from about 100 patients each. Finally, FDA assumed that the remaining 7 drugs would have needed more extensive safety and effectiveness data, requiring 300 pediatric patients for each drug. Consequently, FDA estimates that, if this proposed rule had been in effect from 1991 to 1995, sponsors of 45 of the 60 potentially affected drugs would have needed to obtain additional data from about 5,150 pediatric patients (15 drugs $\times$ 50 patients + 23 drugs $\times$ 100 patients + 7 drugs $\times$ 300 patients). The proposed regulation, therefore, would have required additional pediatric research for an estimated average of 9 new drugs and about 1,030 pediatric patients per year.

In addition, the proposed rule permits the agency to request pediatric data for certain drugs that are already marketed. While the precise impact of this regulatory provision is uncertain, FDA expects that it would affect no more than two drugs per year. If the submission for one of these drugs relied on data from 100 pediatric patients and the other from 300 pediatric patients, the total number of drugs that would have required additional research reaches 11 per year and the total number of pediatric patients about 1,430 per year.

Other costs for pediatric research may accrue to drugs that ultimately fail to gain regulatory approval. Although many drug sponsors would wait until they are relatively certain that their product will be shown safe and effective for the indicated use in adults before

spending substantial resources on pediatric uses, other sponsors may need to begin pediatric examinations earlier to have data included with the new drug or product licence application. It is difficult for FDA to judge how much additional pediatric research would be directed towards products that are not approvable. The agency notes, however, that because only about 65 percent of all NME's that enter phase III trials are eventually approved, the number of drugs entering phase III trials is about 54 percent greater than the number of actual approvals ($100/65 = 1.54$). Since some, but not all, of these unapprovable drugs would initiate some pediatric research, FDA has increased its estimate of the annual number of affected drugs and pediatric patients by 30 percent, to a projected total of 14 drugs and about 1,850 pediatric patients per year.

The agency is aware that forecasting future trends based on historical data can be imprecise. For example, over time, even in the absence of this rule, the percentage of new drugs with labels that provide adequate pediatric use information could change. At this time, however, FDA is not aware of any marked trend. Also, the above estimates ignore those pediatric studies that were promised, but not yet underway at the time of drug approval. To the extent that these commitments are honored, the above estimates of research attributable to the regulation are overstated. Finally, the methodology implies that the standards used by FDA to judge the 1991–1995 approvals would remain unchanged. While subsequent change is possible, FDA does not anticipate that its present views would differ substantially. Thus, while acknowledging substantial uncertainty, the agency's cost estimates are based on the assumption that the proposed rule would require additional research on about 14 drugs, involving a total of 1,850 pediatric patients per year.

C. Cost of Studies

The agency finds that the cost of conducting clinical research with pediatric patients varies directly with the size, duration, and complexity of the clinical research. Although FDA has little detailed information on the cost to drug sponsors of conducting research on clinical patients, one private consulting firm reports that the costs of hiring clinical investigators to conduct phase IV pediatric drug trials ranges from \$300–\$500 per patient for studies on vaccines or fevers to \$3,600 and \$5,000 per patient for renal disease and epilepsy, respectively.³ Similarly, a

number of academic researchers have reported average costs of from \$1,500 to \$3,400 per patient for pediatric trials. These estimates, however, do not account for the many administrative, monitoring, data analysis, and document preparation tasks that would be required of a drug sponsor. Since a published study suggests that a total accounting of all sponsor costs may be three times as great as investigator costs,⁴ FDA has assumed that the average costs of conducting the newly required studies would range from \$5,000 to \$9,000 per pediatric patient. As a result, the estimated 1,850 additional pediatric patients that would need to be studied annually suggests new research costs to the pharmaceutical industry of between \$9.25 million and \$16.65 million per year.

In addition, the testing of a new drug in children would sometimes require the development of a new pediatric dosage form. (Typically a liquid or suspension formulation in place of a tablet or capsule.) Of the 47 drugs identified in the first category of Table 2 (therapeutically important with some potential pediatric use), 14 (30 percent) were available only in tablets or hard capsules at the time of approval. (Manufacturers of 4 of these 14 have since developed oral suspensions.) It seems reasonable, therefore, to assume that, of the 14 new drugs per year estimated to require additional pediatric research, about 4 might require new formulations. The agency solicits comment on the estimate that four new formulations would be required per year.

The effort and cost of developing such formulations could be substantial. Drug developers and manufacturers would have to find appropriate solvents and develop additional data for demonstrating adequate product stability, bioavailability, and production process validation. While such costs would vary with the particular drug type, one industry consultant suggests that per drug laboratory costs could average from \$300,000 to \$500,000 and corresponding regulatory requirements could bring this figure close to \$1 million. Moreover, this estimate assumes the availability of adequate preclinical data on animal toxicity and metabolic rates. Since the proposed rule permits FDA to waive the requirement for reformulation where reasonable attempts have failed, the agency assumes that the additional costs would not exceed \$1 million apiece for 4

⁴ Thomas Hill, "Calculating the Cost of Clinical Research," *Scrip Magazine*, p. 29, March 1994.

³ DataEdge, LLC, Faxed data, March 7, 1997.

drugs, or an additional \$4 million per year.

Finally, the rule will impose additional paperwork burdens related to new label content, postmarket reporting requirements, and written requests for deferred submissions and waivers. As shown above, FDA estimates that these paperwork activities will require about 4,400 hours annually. At an average compensation rate of \$50 an hour, this cost amounts to about \$220,000 per year.

In sum, FDA anticipates that the annual costs of this proposed rule will total between \$13.5 and \$20.9 million per year.

D. Other Impacts

Other potential impacts would occur if the requirements contributed to delays in the submittal of NDA's. Extended drug development times would be associated with significant additional industry costs. FDA has attempted to minimize the likelihood of regulatory delays through plans for early consultation with drug sponsors and a willingness to consider deferred submissions for pediatric studies. However, the agency recognizes the importance of this issue and solicits public comment on the best means to obtain adequate and timely pediatric information without slowing the process for bringing new drugs to market. Also, as noted earlier in this preamble, the agency is aware that new pediatric supplements could impose additional user fees on drug sponsors and is considering means to alleviate this added burden. All user fee issues will be resolved before issuance of the final rule. Overall, therefore, compared to the hundreds of millions of dollars typically required to bring a new drug to market, FDA believes that the added regulatory impact imposed by this rule would be unlikely to threaten the economic viability of any promising research and development project.

E. Benefits

This proposed rule is aimed at addressing two problems associated with inadequate directions for pediatric uses of drugs: (1) Avoidable adverse drug reactions in children, i.e., drug reactions that occur because of the use of inadvertent drug overdoses or other drug administration problems that could have been avoided with better information on appropriate pediatric use; and (2) undertreatment of children with a potentially safe and effective drug, because the physician either prescribed an inadequate dosage or regimen, prescribed a less effective drug, or did not prescribe a drug, due

to the physician's uncertainty about whether the drug or the dose was safe and effective in children. Thus, the primary benefits expected from this proposed rule are the reductions in avoidable adverse drug reactions and undertreatments that would result from better informing physicians about whether, and in what dosages, a given drug was safe and effective for use in children.

FDA is aware of no systematic data in the literature that evaluate the magnitude of harm that results from inadequate information on the use of drugs in children, although numerous anecdotes and case examples exist. Physicians who care for HIV-infected children, for example, have expressed frustration at their inability to treat these children with drugs known to be effective in adults, because they lack information on how to do so safely or effectively.⁵ As mentioned previously in this preamble, history is replete with examples of children who have died or suffered other serious adverse effects as a result of the use of drugs that have not been tested in children and for which better, alternative treatments were available. Many of these adverse events (e.g., "gray baby syndrome" in babies treated with chloramphenicol) develop quickly and would be detected in early clinical studies.

While FDA could not develop a quantitative estimate of the potential benefits of the proposed rule, the agency attempted to gain some more systematic insight into the benefits that might accrue by examining the rate at which each of 20 NME's (approved between 1991 and 1995) were mentioned in the 1996 IMS National Drug and Therapeutics Index (an outpatient drug use data base). The drugs examined were all of those that could be analyzed in this IMS data base, lack full pediatric labeling, were considered to need further pediatric studies at the time of approval, and would have been affected by the proposed rule. FDA found that, after adjusting for the prevalence of the relevant diagnoses in children and adults, 15 of the 20 drugs were mentioned less frequently in association with pediatric treatments than with adult treatments for the same set of approved indications. In 11 of these 15 drugs, pediatric treatment mentions were less than half as frequent. Although it is not possible to conclude, based on these data, that children with those diagnoses are necessarily undertreated relative to adults, these data are consistent with the hypothesis

that the lack of pediatric labeling leads to suboptimal treatment of children.

FDA also examined the number of adverse drug events (ADE's) reported to the agency from 1991 through 1996 for all NME's approved during that time. Of the 25 NME's associated with the highest number of ADE's in children, 8 NME's (responsible for 1,273 pediatric ADE's sufficiently severe to be reported to FDA) had no labeling for use in children at all. An additional 5 NME's (responsible for 434 pediatric ADE's) were labeled for use only in children age 12 and over. Furthermore, of these 13 NME's, 11 would probably have been required to be the subject of further pediatric studies (or of a justification for the lack of studies) under the conditions of this proposed rule if it had been in place at the time of the drug's approval. While it is not possible to conclude that all (or even most) of these ADE's would have been avoided had these drugs been fully labeled for pediatric use, these data confirm that there is substantial pediatric use of drugs not labeled for such use; that this use is associated with ADE's, including serious ADE's; and that the improved knowledge and labeling that would result from this proposed rule could bring significant benefits to children treated with these drugs. The agency solicits information on any available studies or data related to the incidence and costs of either undertreatment or avoidable ADE's in pediatric age groups due to the lack of information on the effects of pharmaceuticals.

F. Small Entities

FDA believes that this proposed rule will not have a significant economic impact on a substantial number of small entities. New drug development is typically an activity completed by large multinational drug firms. FDA reviewed the size of every company that submitted the 60 new drug and biological applications that would likely have been affected by this rule between 1991 and 1995 (see the first two categories in Table 1). Over this 5-year period, only two were for products sponsored by small businesses as defined by the Small Business Administration. Because so few small firms are likely to be significantly affected in any given year, the Commissioner certifies that this rule will not have a significant economic impact on a substantial number of small entities. Therefore, no further analysis is required under the Regulatory Flexibility Act. The agency notes, however, that where pediatric use qualifies as an orphan indication, some of these added research costs could be

⁵Time, March 1997.

reimbursed under the various grant and tax deduction provisions of the Orphan Drug Act.

XI. Request for Comments

Interested persons may, on or before November 13, 1997, 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Submit written comments on the information collection provisions 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.

XII. 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.

1. Committee on Drugs, American Academy of Pediatrics, Guidelines for the Ethical Conduct of Studies to Evaluate Drugs in Pediatric Populations, *Pediatrics*, 95(2):286-294, 1995.

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8. Nathan, D. G. et al., *Hematology of Infancy and Childhood*, 4th Edition, W. B. Saunders Co., Philadelphia, p. 92, 1993.

9. Kauffman, R. E., "Fentanyl, fads, and folly: who will adopt the therapeutic orphans?" *Journal of Pediatrics*, 119:588-589, 1991.

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16. Hiller, A. et al., "Unconsciousness associated with midazolam and erythromycin," *British Journal of Anaesthesia*, 65:826-828, 1994.

List of Subjects

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, and Safety.

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

Therefore under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 201, 312, 314, and 601 be amended as follows:

PART 201—LABELING

1. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 508, 510, 512, 530-542, 701, 704, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 358, 360, 360b, 360gg-360ss, 371, 374, 379e); secs. 215, 301, 351, 361 of the Public Health Service Act (42 U.S.C. 216, 241, 262, 264).

2. New § 201.23 is added to subpart A to read as follows:

§ 201.23 Required pediatric studies.

(a) A manufacturer of a drug product, including a biological drug product, that is widely used in pediatric patients, or that is indicated for a very significant or life threatening illness, but whose label does not provide adequate information to support its safe and effective use in pediatric populations for the claimed indications may, in compelling circumstances, be required to submit an application containing data adequate to assess whether the drug product is safe and effective in pediatric populations. The application may be required to contain adequate evidence to support dosage and administration in some or all pediatric subpopulations, including neonates, infants, children, and adolescents, depending upon the known or appropriate use of the drug product in such subpopulations. The applicant may be required to develop a pediatric formulation for a drug product that is indicated for a very significant or life threatening illness for which a pediatric formulation is necessary, unless the manufacturer demonstrates that reasonable attempts to produce a pediatric formulation have failed.

(b) The Food and Drug Administration (FDA) may, by order issued by the Center for Drug Evaluation and Research (CDER) or Center for Biologic Evaluation and Research (CBER) Center Director, after notifying the manufacturer of its intent and offering an opportunity for a written response and a meeting, which may include an advisory committee meeting, require a manufacturer to submit an application containing the information described in paragraph (a) of this section within a time specified in the letter, if FDA finds that:

(1) The drug product is widely used in pediatric populations for the claimed indications and the absence of adequate labeling could pose significant risks to pediatric patients; or

(2) The drug product is indicated for a very significant or life threatening illness, but additional dosing or safety information is needed to permit its safe and effective use in pediatric patients.

(c)(1) FDA may grant a full or partial waiver of the requirements of paragraph (a) of this section on its own initiative or at the request of an applicant.

(2) An applicant may request a full waiver of the requirements of paragraph (a) of this section if the applicant certifies that:

(i) Necessary studies are impossible or highly impractical, e.g., because the number of such patients is so small or geographically dispersed; or

(ii) There is evidence strongly suggesting that the drug product would

be ineffective or unsafe in all pediatric age groups.

(3) An applicant may request a partial waiver of the requirements of paragraph (a) of this section with respect to a specified pediatric age group, if the applicant certifies that:

(i) The drug product:

(A) Is not indicated for a very significant or life threatening illness; and

(B) Is not likely to be used in a substantial number of patients in that age group; or

(ii) Necessary studies are impossible or highly impractical because, e.g., the number of patients in that age group is so small or geographically dispersed; or

(iii) There is evidence strongly suggesting that the drug product would be ineffective or unsafe in that age group; or

(iv) The applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

(4) The request for a waiver must provide an adequate justification.

(5) FDA shall grant a full or partial waiver, as appropriate, if the agency finds that there is a reasonable basis on which to conclude that one or more of the grounds for waiver specified in paragraph (c)(2) or (c)(3) of this section have been met. If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver will cover only those pediatric age groups requiring that formulation. If a waiver is granted because there is evidence that the product would be ineffective or unsafe in pediatric populations, this information will be included in the product's labeling.

(d) If a manufacturer fails to submit a supplemental application containing the evidence described in paragraph (a) of this section within the time specified by FDA, and the Center Director of CDER or CBER, under the requirements of paragraph (c) of this section, has not granted a waiver, the drug product may be considered misbranded or an unapproved new drug.

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

3. The authority citation for 21 CFR part 312 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371); sec. 351 of the Public Health Service Act (42 U.S.C. 262).

4. Section 312.23 is amended by redesignating paragraph (a)(10)(iii) as paragraph (a)(10)(iv) and adding new paragraph (a)(10)(iii) to read as follows:

§ 312.23 IND content and format.

(a) * * *

(10) * * *

(iii) *Pediatric studies.* If the drug is a new chemical entity, plans for assessing pediatric safety and effectiveness.

* * * * *

5. Section 312.47 is amended by revising paragraph (b)(1)(i) and the second sentence of paragraph (b)(2) and by adding a new sentence after the fifth sentence to paragraph (b)(1)(v) to read as follows:

§ 312.47 Meetings.

* * * * *

(b) * * *

(1) *End-of-Phase 2 meetings—(i) Purpose.* The purpose of an end-of-phase 2 meeting is to determine the safety of proceeding to phase 3, to evaluate the phase 3 plan and protocols and the adequacy of plans to assess pediatric safety and effectiveness, and to identify any additional information necessary to support a marketing application for the uses under investigation.

* * * * *

(v) *Conduct of meeting.* * * * FDA will also provide its best judgment, at that time, of the pediatric studies that will be required for the drug product and their timing. * * *

(2) *“Pre-NDA” meetings.* * * * The primary purpose of this kind of exchange is to uncover any major unresolved problems, to identify those studies that the sponsor is relying on as adequate and well-controlled to establish the drug's effectiveness, to identify current or planned studies adequate to assess pediatric safety and effectiveness, to acquaint FDA reviewers with the general information to be submitted in the marketing application (including technical information), to discuss appropriate methods for statistical analysis of the data, and to discuss the best approach to the presentation and formatting of data in the marketing application. * * *

* * * * *

6. Section 312.82 is amended by revising the last sentence of paragraph (a) and the second sentence of paragraph (b) to read as follows:

§ 312.82 Early consultation.

* * * * *

(a) *Pre-investigational new drug (IND) meetings.* * * * The meeting may also provide an opportunity for discussing the scope and design of phase 1 testing, plans for studying the drug product in pediatric populations, and the best approach for presentation and formatting of data in the IND.

(b) *End-of-phase 1 meetings.* * * * The primary purpose of this meeting is to review and reach agreement on the design of phase 2 controlled clinical trials, with the goal that such testing will be adequate to provide sufficient data on the drug's safety and effectiveness to support a decision on its approvability for marketing, and to discuss the need for, as well as the design and timing of, studies of the drug in pediatric patients. * * *

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG

7. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701, 704, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371, 374, 379e).

8. Section 314.50 is amended in subpart B by redesignating paragraphs (g) through (k) as paragraphs (h) through (l) and by adding new paragraphs (d)(7) and (g) to read as follows:

§ 314.50 Content and format of an application.

* * * * *

(d) * * *

(7) *Pediatric use section.* A section describing the investigation of the drug for use in pediatric populations, including an integrated summary of the information (the clinical pharmacology studies, controlled clinical studies, or uncontrolled clinical studies, or other data or information) that is relevant to the safety and effectiveness and benefits and risks of the drug in pediatric populations for the claimed indications, and a reference to the full descriptions of such studies provided under paragraphs (d)(3) and (d)(5) of this section.

* * * * *

(g) *Pediatric use information—(1) General requirements.* Except as provided in paragraphs (d)(2) and (d)(3) of this section, each application for a new chemical entity shall contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in pediatric populations, including neonates, infants, children, and adolescents, and to support dosing and administration information for each pediatric subpopulation for which the drug is safe and effective. Where the course of the disease and the effects of the drug are sufficiently similar in adults and pediatric patients, FDA may conclude that pediatric effectiveness can be extrapolated from adequate and well-

controlled studies in adults based on other information, such as pharmacokinetic studies. Studies may not have to be carried out in each pediatric age group, if data from one age group can be extrapolated to others. Assessments of safety and effectiveness required under this section for a drug product that represents a meaningful therapeutic benefit over existing treatments for pediatric patients must be carried out using appropriate formulations for each age group(s) for which the assessment is required.

(2) *Deferred submission.* FDA may, on its own initiative or at the request of an applicant, defer submission of some or all assessments of safety and effectiveness described in paragraph (g)(1) of this section until after approval of the drug product for use in adults. If an applicant requests deferred submission, the request must provide a certification from the applicant of the grounds for delaying pediatric studies, a description of the planned or ongoing studies, and evidence that the studies are being or will be conducted with due diligence and at the earliest possible time. If FDA determines that there is an adequate justification for temporarily delaying the submission of assessments of pediatric safety and effectiveness, the drug product may be approved for use in adults subject to the requirement that the applicant submit the required assessments within a specified time.

(3) *Waivers*—(i) FDA may grant a full or partial waiver of the requirements of paragraph (g)(1) of this section on its own initiative or at the request of an applicant.

(ii) An applicant may request a full waiver of the requirements of paragraph (g)(1) of this section if the applicant certifies that:

(A) The drug product:

(1) Does not represent a meaningful therapeutic benefit over existing treatments for pediatric patients; and

(2) Is not likely to be used in a substantial number of pediatric patients; or

(B) Necessary studies are impossible or highly impractical, e.g., because the number of such patients is so small or geographically dispersed; or

(C) There is evidence strongly suggesting that the drug product would be ineffective or unsafe in all pediatric age groups.

(iii) An applicant may request a partial waiver of the requirements of paragraph (g)(1) of this section with respect to a specified pediatric age group, if the applicant certifies that:

(A) The drug product:

(1) Does not represent a meaningful therapeutic benefit over existing

treatments for pediatric patients in that age group; and

(2) Is not likely to be used in a substantial number of patients in that age group; or

(B) Necessary studies are impossible or highly impractical because, e.g., the number of patients in that age group is so small or geographically dispersed; or

(C) There is evidence strongly suggesting that the drug product would be ineffective or unsafe in that age group; or

(D) The applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

(iv) The request for a waiver must provide an adequate justification.

(v) FDA shall grant a full or partial waiver, as appropriate, if the agency finds that there is a reasonable basis on which to conclude that one or more of the grounds for waiver specified in paragraph (g)(2) or (g)(3) of this section have been met. If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver will cover only those pediatric age groups requiring that formulation. If a waiver is granted because there is evidence that the product would be ineffective or unsafe in pediatric populations, this information will be included in the product's labeling.

* * * * *

9. Section 314.81 is amended by adding two new sentences at the end of paragraph (b)(2)(i) and a new paragraph (b)(2)(vi)(c) and by revising paragraph (b)(2)(vii) to read as follows:

§ 314.81 Other postmarketing reports.

* * * * *

(b) * * *

(2) * * *

(i) *Summary.* * * * The summary shall briefly state whether labeling supplements for pediatric use have been submitted and whether new studies in the pediatric population to support appropriate labeling for the pediatric population have been initiated. Where possible, an estimate of patient exposure to the drug product, with special reference to the pediatric population (neonates, infants, children, and adolescents) should be provided, including dosage form.

* * * * *

(vi) * * *

(c) Analysis of available safety and efficacy data conducted or obtained by the applicant in the pediatric population and changes proposed in the label based on this information. An assessment of data needed to ensure appropriate labeling for the pediatric population should be included.

(vii) *Status reports.* A statement on the current status of any postmarketing studies performed by, or on behalf of, the applicant. The statement shall include the status of postmarketing clinical studies in pediatric populations required or agreed to, e.g., to be initiated, ongoing (with projected completion date), completed (including date), completed and results submitted to the NDA (including date). To facilitate communications between FDA and the applicant, the report may, at the applicant's discretion, also contain a list of any open regulatory business with FDA concerning the drug product subject to the application.

* * * * *

PART 601—LICENSING

10. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 513–516, 518–520, 701, 704, 721, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381); secs. 215, 301, 351, 352 of the Public Health Service Act (42 U.S.C. 216, 241, 262, 263); secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461).

11. New § 601.27 is added to subpart C to read as follows:

§ 601.27 Pediatric studies.

(a) *General requirements.* Except as provided in paragraphs (b) and (c) of this section, each application for a new biological product for which the applicant has not previously obtained approval shall contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in pediatric populations, including neonates, infants, children, and adolescents, and to support dosing and administration information for each pediatric subpopulation for which the product is safe and effective. Where the course of the disease and the effects of the product are similar in adults and pediatric patients, FDA may conclude that pediatric effectiveness can be extrapolated from adequate and well-controlled effectiveness studies in adults, based on other information, such as pharmacokinetic studies. In addition, studies may not have to be carried out in each pediatric age group, if data from one age group can be extrapolated to others. Assessments required under this section for a product that represents a meaningful therapeutic benefit over existing treatments must be carried out using appropriate formulations for the age group(s) for which the assessment is required.

(b) *Deferred submission.* FDA may, on its own initiative or at the request of an applicant, defer submission of some or all assessments of safety and effectiveness described in paragraph (a) of this section until after licensing of the product for use in adults. If an applicant requests deferred submission, the request must provide an adequate justification for delaying pediatric studies, a description of the planned or ongoing studies, and evidence that the studies are being or will be conducted with due diligence and at the earliest possible time. If FDA determines that there is an adequate justification for temporarily delaying the submission of assessments of pediatric safety and effectiveness, the product may be licensed for use in adults subject to the requirement that the applicant submit the required assessments within a specified time.

(c) *Waivers.* (1) FDA may grant a full or partial waiver of the requirements of paragraph (a) of this section on its own initiative or at the request of an applicant.

(2) An applicant may request a full waiver of the requirements of paragraph (a) of this section if:

(i) The product:

(A) Does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and

(B) Is not likely to be used in a substantial number of pediatric patients; or

(ii) Necessary studies are impossible or highly impractical because, e.g., the number of such patients is so small or geographically dispersed; or

(iii) There is evidence strongly suggesting that the product would be ineffective or unsafe in all pediatric age groups.

(3) An applicant may request a partial waiver of the requirements of paragraph (a) of this section with respect to a specified pediatric age group, if:

(i) The product:

(A) Does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and

(B) Is not likely to be used in a substantial number of patients in that age group; or

(ii) Necessary studies are impossible or highly impractical, e.g., because the number of patients in that age group is so small or geographically dispersed; or

(iii) There is evidence strongly suggesting that the product would be

ineffective or unsafe in that age group; or

(iv) The applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

(4) The request for a waiver must provide an adequate justification.

(5) FDA shall grant a full or partial waiver, as appropriate, if the agency finds that there is a reasonable basis on which to conclude that one or more of the grounds for waiver specified in paragraph (c) (2) or (3) of this section have been met. If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver will cover only those pediatric age groups requiring that formulation. If a waiver is granted because there is evidence that the product would be ineffective or unsafe in pediatric populations, this information will be included in the product's labeling.

Dated: July 24, 1997.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 97-21646 Filed 8-13-97; 2:00 pm]

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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.

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